

EXHIBIT 5

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| In re: PHARMACEUTICAL INDUSTRY) | |
| AVERAGE WHOLESALE PRICE) | |
| LITIGATION) | MDL No. 1456 |
| _____) | Civil Action No. 01-12257-PBS |
| THIS DOCUMENT RELATES TO:) | Hon. Patti Saris |
|) | |
| <i>United States of America ex rel. Ven-a-Care of)</i> | Magistrate Marianne Bowler |
| <i>the Florida Keys, Inc., v. Abbott Laboratories,)</i> | |
| <i>Inc.</i>) | |
| CIVIL ACTION NO. 06-11337-PBS) | |

DECLARATION OF LESLIE V. NORWALK

I, Leslie V. Norwalk, declare as follows:

1. I am the Acting Administrator of the Centers for Medicare & Medicaid Services ("CMS"), which is a component of the Department of Health and Human Services ("HHS" or the "agency"). I have been with CMS since November 2001. I have been the Acting Administrator since October 2006. I was the Deputy Administrator from July 2004 to October 2006. Prior to that, I served as Acting Deputy Administrator and Chief Operating Officer, and, before that, I served as counselor to the CMS Administrator. I also served in the White House Office of Presidential Personnel during the first Bush Administration, and I have practiced law in the Washington, D.C. office of the law firm of Epstein Becker & Green.

2. As the Acting Administrator of CMS, I share overall responsibility for the administration of all federal health care financing programs under Titles XI, XVIII, XIX, and XXI of the Social Security Act, including authority over agency records. Title XVIII is the Medicare Program.

Title XIX is the Medicaid program. The Secretary of HHS has delegated to the CMS Administrator his authority under 42 U.S.C. § 1306 to disclose to the public information pertinent to the mission of CMS, as well as the authority of the Secretary under the Medicaid statute. 49 Fed. Reg. 35,248 (Sept. 6, 1984), as amended at 66 Fed. Reg. 35,437 (July 5, 2001)

3. I am informed that documents in the possession of CMS and the agency have been requested in the course of the above-captioned litigation. These documents are described on two privilege logs that have been served on defendants (The "Privilege Logs"). One log covers documents that came from CMS. The other log covers documents which were withheld from the production of documents which came from contractors ("carriers") with which CMS contracts to administer payment under Part B of the Medicare Program. Except as noted, all references to the Privilege Logs contained in this declaration refer to either one or both of those logs.

4. I understand that these documents were sought, first, by third-party subpoenas served in the above-captioned MDL proceeding in 2003 and, are also now the subject of discovery requests served upon the United States pursuant to Fed. R. Civ. Proc. 34 in a case or cases in which the United States is a party.

5. The Privilege Logs contain entries for 451 documents. There are 382 entries on the CMS log and 69 entries on the carrier log. The documents referenced on the Privilege Logs were created over an eighteen year time span from 1984 to 2002. As a consequence of the broad scope of the subpoenas served on the Government in 2004, the documents came from numerous sections and offices within CMS, relate to a wide range of subjects and cover an expansive time frame.

6. For the time period at issue in this litigation, only certain drugs were covered under Medicare's Part B. In connection with its responsibility to administer payment for Part B drugs, the

agency necessarily considered and analyzed issues that came up regarding the coverage and reimbursement for these drugs. The agency also was called upon to respond to public and provider questions about Medicare's coverage of and payment for drugs, as well Congressional inquiries. The documents contained on the CMS privilege log include those setting forth internal discussions of Part B drug coverage and payment issues at all levels of CMS. Such discussions include those weighing the pros and cons of implementing new reimbursement methodologies, deliberations concerning how to appropriately respond to provider and congressional inquiries, and internal debates pertinent to coverage issues. Final agency positions resulting from those discussions are evidenced by Congressional testimony and formal agency reports to Congress, letters to outside entities, agency publications, and Federal Register notices.

7. CMS also has certain program and payment responsibilities in the area of Medicaid reimbursement for drugs. The Medicaid Drug Rebate Program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) for states to receive Federal funding for outpatient drugs dispensed to Medicaid patients. The drug rebate program is administered by the Centers for Medicare & Medicaid Services' Center for Medicaid and State Operations (CMSO). The states may also have supplemental rebate programs which are reviewed and approved by CMS through the state plan amendment process.

Assertion of the Deliberative Process Privilege

8. I hereby assert a formal claim of the deliberative process privilege over the documents described on the Privilege Logs. This assertion is based on my personal review of each of the entries in the Privilege Logs served on defendants. I have also personally reviewed a sampling of the documents described on the Privilege Logs. My statements in this declaration also are based upon information

personally known to me or conveyed to me by agency personnel who have reviewed every one of the documents for which the privilege is being asserted.

9. In the paragraphs below, I specify why I believe that the information for which I am asserting the deliberative process privilege properly falls within the scope of the privilege. I have determined that the documents are pre-decisional and deliberative and should be withheld from disclosure in the public interest. Because there are many documents in the Privilege Log, I have divided the documents into general categories which I will describe in greater detail in the ensuing paragraphs.

10. Drafts – A substantial portion of the documents on the Privilege Logs consist of internal drafts of CMS, HHS Office of Inspector General, and carrier documents. The draft documents are in a variety of forms, cover a diverse set of subject areas, and include draft OIG reports, draft policy statements, draft speeches, draft regulations, and draft correspondence. Many of the draft documents contain handwritten suggestions for changes or proposed alterations. Many of the other draft documents are preliminary, pre-publication statements of agency policy. Examples from this the first category, draft documents follow:

- a. HHC901-03600365: A draft memorandum discussing the proposed establishment of a Medicare Single Drug Pricer (SDP). The draft contains the author's preliminary recommendations concerning the establishment of an SDP for drugs covered under Medicare Part B. The Memorandum was authored by Thomas Grissom of CMS for Thomas Scully the Administrator of CMS.
- b. HHC003-01140115: A draft letter prepared by Mark E. Miller, Ph. D., Deputy Director Center for Health Plans and Providers, CMS to be sent to N.M. Kotecha, M.D. The draft discusses the potential use by CMS contractors of

AWP data obtained by the Department of Justice. The data could be used by the contractors to determine drug prices for January 2001. There is also a discussion of Congressional involvement in drug pricing initiatives. The document is a draft letter, and does not reflect, in its draft form, the final view of the agency or CMS on these issues. Frequently as these drafts go through an agency clearance process they are modified to reflect an agency wide view.

- c. HHC901-09730975: A draft options paper regarding the implementation of the AWP for drugs provided by DOJ (with handwritten notes). The options paper contains suggestions and comments on the pros and cons of using the DOJ data and also possible alternatives to using the DOJ data. The document is clearly pre-decisional and does not reflect any final agency decision on the issue. The paper was authored by Robert Berenson, Director, Center for Health Plans and Providers for the CMS Administrator.
- d. HHC906-05910592: Draft letter request for information from Montana regarding its proposed state plan amendment (SPA) 03-002. The amendment proposes to change the reimbursement methodology for the Estimated Acquisition Cost representing Average Wholesale Price. The letter was authored by Larry Reed, Co-Director of the Pharmacy Team, CMSO, CMS.

11. Internal Memoranda and Notes – Another large category of documents on the Privilege Log consists of internal CMS and carrier memoranda, reflecting deliberations concerning HHS policy decisions or potential HHS actions. Some of the documents in this category take the form of notes from agency personnel containing comments and recommendations regarding the manner in which

CMS should respond to a public inquiry or articulate a policy. The memoranda and notes cover a diverse range of topics, but have in common the fact that they contain proposals, recommendations, or advice about future HHS action. Examples from this second category follow.

- a. HHC901-07100715 (released 711, 713 & 715) - Draft Memorandum regarding Medicare payments for drugs using Department of Justice (DOJ) AWP data. The memorandum contains updates regarding progress in utilizing the DOJ AWP data. The memorandum is pre-decisional and does not reflect the agency's final decision on the issue. The draft memorandum was authored by Michael Hash, Deputy Administrator of CMS and addressed to Kevin Thurm, Deputy Secretary of HHS.
- b. HHC906-00900091: Medicare drug pricing memorandum which discusses whether an Notice of Proposed Rulemaking should include drugs in the Physician Fee Schedule and payment for drugs at AWP minus 15%. The memorandum contains suggestions for additional changes to drug pricing policy. The memorandum reflects the deliberations of the agency and does not represent a final decision on the issue of inclusion of drugs in the Physician fee Schedule. The memorandum was authored by Kathleen Buto, Director, Bureau of Policy Development to the Associate Regional Administrator, Division of Medicare, Dallas.
- c. HHC903-0935: Note discussing Lupron expenditures. The note contains a discussion of recent developments regarding medical necessity and how those development impact CMS policy on a going forward basis. The note does not

contain a final agency decision on the subject of pricing for Lupron. The note was authored by Charles Booth. The note is dated 01/ /1994.

12. Notes from Meetings and Meeting Minutes – Another category of documents on the Privilege Log consists of meeting minutes or notes from consultative meetings among CMS or carrier employees. These documents describe the positions taken at such meetings by various agency or carrier personnel, and thus reflect the internal advice pertaining to a variety of policy decisions or agency actions. Other entries on both logs recount discussions involving pre-decisional opinions and suggestions of agency personnel, and as such, fall within the deliberative process privilege. Examples from this third category follow.

- a. HHC906-01240125: Notes from a conversation between Mark Vogel, CMS, Marvin Stoogenke, CMS pharmacist and Laura Brooks, United Healthcare, as an agent of CMS. The notes contain discussions regarding proposed changes to pricing multiple source generics. The discussion are clearly pre-decisional in nature and do not represent a final agency decision on the issue of generic drug pricing.
- b. HHC906-01870189: Notes from a conference call between Terrence Kay, CMS, Stanley Weintraub, CMS and Jim Menas, CMS. The notes include a discussion of proposed resource based practice expense relative value units (RVUs). The note contains suggestions as to what should be included in the RVU, i.e., supplies and salaries and methods for deriving costs for those components. The note reflects ongoing discussions and does not represent any final agency decision.

13. E-Mails – A small number of internal e-mails are included on the Privilege Log. The e-mails contain advice and recommendations concerning future CMS or carrier action. Many of the e-mails on our privilege logs consist of print-outs with handwritten notes and marginalia commenting on the content of the e-mails. Examples from this fourth category follow.

- a. HHC901-0877: E-mail discussing a comparison between Lupron and Zoladex. The e-mail contains a discussion of confidentiality of certain FDA data and suggestions of alternative data to use when comparing the two drugs. From Jean Fourcroy, FDA to Constance Conrad, CMS.
- b. HHC901-08430844: E-mail (with hand written notes) discussing concerns regarding Local Medical Review Policy 97-01-D for Lupron. The e-mail also contains a discussion of CMS' proposed policy change in payment for Lupron and Zoladex. The e-mail is from David Sheridan, [M.D., Palmetto GBA] to Robert Niemann, CMS.

14. Briefing and Analytical Materials – Several of the Privilege Log entries consist of briefing materials for senior CMS personnel developed in advance of meetings, and as such, reflect internal advice concerning the agency's public statements on policy issues. Other documents contain descriptions of sampling methodologies. This last category of documents is small, consisting of no more than 20 documents out of over 400 contained on the two logs. Examples from this fifth category follow.

- a. HHC006-02990302: CMS' internal analysis of Connecticut State Plan Amendment No. 03-002. The analysis includes a discussion of proposed state payment methodology for Medicaid drugs and suggestions for modifications and

additional information. This analysis was authored by Tieng Chong, Health Insurance Specialist, CMS and sent to Carl Tepper, Pharmacist, CMS and Irv Rich, Health Insurance Specialist, CMS.

- b. HHC902-00590062: Briefing material for the CMS Administrator discussing proposals, pros/cons, and potential effects of changes in the following policies: independent physiological labs - physician supervision of diagnostic test, physician fee schedule payment areas, and alternative reimbursement mechanisms. The memorandum contains a proposal to use the actual acquisition cost instead of the current methodology of basing payment for drugs on the lowest of the actual charge, median AWP, or the estimated acquisition cost (EAC).
- c. HHC902-00940097: Memorandum regarding an upcoming meeting. Attachments contain talking points regarding alternative Medicare Part B reimbursement mechanisms and the pros/cons and potential impact of each. Also contains talking points regarding waste and spoilage concerns for chemotherapy drugs. Authored by Bernadette Schumaker, CMS and sent to Charlie Spalding, "Pat," Robert Niemann, and "Dorothy."

15. Based on the duties I currently perform, and based on my experience in previous positions I have held, I am familiar with the deliberative and decision-making processes within CMS. Based on my personal knowledge of these deliberative and decision-making processes, I believe that the information set out in the Privilege Logs attached to this declaration are deliberative in nature. I believe that this agency has a responsibility to soundly administer the programs for which it has responsibility.

Promoting the free exchange of views about how to best accomplish this responsibility is an important part of our internal operations.

16. Given the broad time frame and range of topics covered by the documents on the Privilege Logs, the manner of deliberation and the context in which it occurred, of course, considerably varied from subject to subject. Some of the documents may contain reflections and statements that reflect an official's personal perspective or view. The notes, comments, and recommendations that I and my staff have reviewed and considered reflect the types of exchanges that occur within CMS when establishing, amending, and fine-tuning the policies and procedures required to effectively and efficiently administer both the Medicare and Medicaid programs. I also believe that agency personnel, when they discuss matters related to improvement of the policies and procedures which are in place, reasonably expect that the substance of their discussions will be kept confidential in order to ensure a free flow of candid advice and analysis.

17. It is also very important to bear in mind that unpublished drafts reflecting the opinions or suggestions of the author(s) and the comments from other CMS staff directed at or relating to those draft documents do not constitute the final position of the agency on any matter unless and until they are embodied in or adopted in a final decision issued by an official with authority to speak for the agency on a given topic or question. I also believe that the release of documents which contain statements or opinions by personnel which were then rejected or revised during later discussions and deliberations among agency decision-makers could disrupt and even harm the agency's mission from the dissemination of inaccurate and incomplete information. The overarching purpose of all reviews, considerations, and deliberations undertaken by the agency at every level is to ensure that the agency issue final statements regarding its policies and decisions and that they are in accordance with

controlling statutes, regulations, and objectives. Consistent with that purpose, the agency must be careful that every statement which it releases accurately articulates the agency's position on any given issue or question. Effective policy-making requires the consideration of alternative and even competing goals and ways to accomplish the agency's mission. The suggestions and alternatives which are the subject of the deliberations should never be confused with actual, final, agency policy or procedure adopted at the conclusion of the deliberations.

18. In order to make fully informed decisions, I, and other senior CMS staff, must be able to rely on our staff to provide recommendations and advice to us on all matters which may affect the efficient administration of the programs for which we are responsible. The recommendations and advice must be frank if they are to have value. I rely on agency personnel to be candid with all persons who are working for the agency.

19. I know from my own experience that the administration of the Medicare and Medicaid programs presents issues that require discussion among government employees. A frank exchange of ideas, views about governing principles, precedent and goals concerning these subjects as well as the consideration of alternative policies or solutions is necessary and desirable if these deliberations are to be useful.

20. Based on my experience, I believe that open, candid exchanges of ideas and information among CMS personnel regarding the effective administration of the agency would be seriously inhibited if the officials believed that their internal discussions, analyses, opinions, views and recommendations would be disclosed publicly. I believe that if the discussions and recommendations contained or referenced in the documents attached to this declaration were subject to public disclosure, CMS personnel officials would feel constrained in their deliberations because we would have no confidence

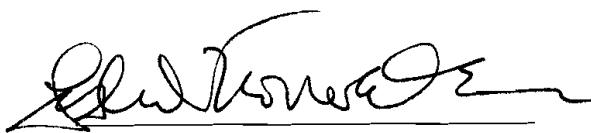
that our internal discussions would remain confidential.

21. I believe the foregoing concerns about the potential chilling effect on the candid exchange of opinions and recommendations on agency personnel are heightened in the context of litigation, especially any case in which the Government is a party. As a lawyer who has considerable experience in both private practice and government service, I am certain that the prospect of a critical examination and dissection of one's comments or criticisms, whether reflected in an email, memorandum or in the marginalia of a document, during litigation will have a profound and detrimental impact on the free exchange of candid commentary among employees – especially with regard to those individuals who would otherwise be inclined to express critical or minority opinions.

22. For the reasons stated above, I consider that the release of the documents I are described on CMS's privilege log would be detrimental to CMS deliberations and thus contrary to the public interest. I therefore respectfully assert the privilege for governmental deliberative communications to withhold those documents from disclosure to the defendants.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 20 day of April, 2007 in Washington, DC.



CMS PRIVILEGE LOG

Amended CMS Privilege Log 2004 Production

| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|---|-------------------------|----------------|---|---|-----------------------------|--|--|------------------------------------|---|
| HHC001-04600460 (Last 3 para. Redacted) | 12/19/1996 | E-mail | Discussion after meeting with Hogan & Hartson about payment for Lupron and Zolodex. | Ault, Thomas | | Schumaker, B., Niemann, R., Bagley, G, | | McCann, B., Wynn, B., Sheingold S. | DP Deliberative Process |
| HHC002-0380380 | 09/14/1992 | Letter | Draft of Response to Eli Lilly Concerning Medicaid Drug Rebate Payments. This is a discussion between attorney and client about the Medicaid drug rebate statute and how to respond to an inquiry from Eli Lilly. | Salhus, Mary | Attorney, OGC | Reed, Larry | | | AC Attorney-Client, DP Deliberative Process |
| HHC002-03810382 | 09/14/1992 | Letter | Draft of Response to Eli Lilly Concerning Medicaid Drug Rebate Payments. This is a discussion between attorney and client about the Medicaid drug rebate statute and how to respond to an inquiry from Eli Lilly. | Salhus, Mary | Attorney, OGC | Reed, Larry | | | AC Attorney - Client, DP Deliberative Process |
| HHC002-03830383 | XX/XX/XXXX | Memo | Internal discussion regarding advice given by OGC. Contains discussion of interpretation of the Medicaid drug rebate statute. | | | | | | DP Deliberative Process |
| HHC003-01140115 | Approximately 2000-2001 | Draft Letter | Discusses the use of alternative AWP data obtained by the Department of Justice. | Miller, Mark E., PH.D., Center for Health Plans and Providers | Deputy Director | Kotecha, N.M., MD | | | DP Deliberative Process |
| HHC003-01210124 | Approximately 2000-2001 | Draft Letter | Discusses the use of alternative AWP data obtained by the Department of Justice. Also discusses past Medicare drug payment policy. | Miller, Mark E., PH.D., Center for Health Plans and Providers | Deputy Director | Bromberg, Warren D., MD, Mount Kisco Medical Group | | | DP Deliberative Process |
| HHC003-04180419 | XX/XX/XXXX | Appendix 1 | Description of sampling used to develop nationwide estimates of prices paid for brand name drugs | | | | | | DP Deliberative Process |
| HHC003-04200421 | XX/XX/XXXX | Appendix 2 | Nationwide AWP Sample Results Brand Name Drugs | | | | | | DP Deliberative |
| HHC004-02290239 | XX/XX/XXXX | Draft | Draft OIG Report; Medicaid Pharmacy--Actual Acquisition Cost of Prescription Drug Products, (A-06-00-00023) | DHS | Office of Inspector General | | | | DP Deliberative Process |
| HHC006-02999302 | XX/XX/XXXX | Analysis Sheet | Internal Analysis of Connecticut State Plan Amendment No. 03-002. Analysis of proposed state payment methodology for Medicaid drugs. | Tieng, Chong B. | Health Insurance Specialist | Tepper, Carl; Rich, Irv | Pharmacist, HealthInsurance Specialist | | DP Deliberative Process |

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| HHC009-01760177 | XX/XX/XXXX | Memo | Michigan SPA 01-15 And Supplemental Rebate. OGC review of state's proposal to amend their drug reimbursement methodology and how it calculates its supplemental rebates. | Sailhus, Mary; Lyons, Susan Maxson | Attorneys, OGC | Howell, Kim | | | AC Attorney-Client |
| HHC011-20422046 | 01/25/1990 | Memorandum | Legal opinion of Proposed Arkansas Medicaid Disallowance Of Prescription Drug Claim (Your Reference AR/90/002/MAP) | Kermit Fonteno, | Attorney, Office Of The General Counsel Region VI | Sconce, J. D., | Health Care Financing Administration Region VI | Regional Administrators : Boston, New York, Philadelphia, Atlanta, Chicago | AC Attorney-Client |
| HHC015-12631263 | XX/XX/XXXX | E-mail | Discussion of former inquiries with OGC regarding TAP litigation and use of least costly alternative policy. | Burgess, Sharon | | NHIC-M | | | AC Attorney-Client |
| HHC901-00930133 (Released 0131-33) | XX/XX/XXXX | Memo with Attachments | Request for a Modification to Contract #500-96-0026, Task order #17 re: Prices Established by the Private and Public Sectors for Drugs also Covered Under Medicare Part B | Stoogenke, Marvin M., HCFA | Project Officer, Division of Supplier Claims Processing, Center of Health Plans and Providers | | Director, HCFA, Div. of Research Contracts and Grants, Acquisition and Grants Group | | DP Deliberative Process |
| HHC901-01760184 | XX/XX/XXXX | Contract Document | Proposed contract to Develop Electronic Drug Pricing Containing Reimbursement Allowances for Drugs Covered Under the Medicare Program by developing an AWP for covered drugs | Broseker, Joseph, HHS | Dep. Director in CCHP | Pritchett, Jacqueline | | Stoogenke, Marvin | DP Deliberative Process |
| HHC901-02210222 | 2000 | Notes | Response to recent communications with handwritten comments regarding using NDC's as identifiers, draft manual instructions regarding drug pricing, and crosswalk for drug pricing. | | | | | | DP Deliberative Process |
| HHC901-03600365 | 2000 | Memo with Attachment | Draft of memo Establishing a Medicare Single Drug Pricer (SDP) and changing how Medicare reimburses for drugs - Advisory | Grissom, Tom | | Scully, Tom | | | DP Deliberative Process |
| HHC901-06680680 | 2001 | Draft | Draft GAO Report with notes re Pricing of Medicare's Part B-covered Prescription Drugs as directed by the SCHIP Improvement Act (P.L. 106-554). | | | | | | DP Deliberative Process, AC Attorney-Client |

Amended CMS Privilege Log 2004 Production

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| HHC901-06890710 | 2000 or 2001 | Draft Program Memorandum with Attachment | Intermediaries/Carriers - A More accurate source of Average Wholesale Data (Attached) in Pricing Drugs and Biologicals covered by the Medicare Program. Related to AB-00-86 | HCFA | | | | | DP Deliberative Process |
| HHC901-07110715 (Released 711, 713 & 715) | 2000 or 2001 | Memo with Attachment | Medicare Payments for Drugs Using Department of Justice Data | Hash, Michael | Deputy Administrator | Thurm, Kevin | Deputy Secretary | | DP Deliberative Process |
| HHC901-07160723 | 2000 or 2001 | Program Memorandum Intermediaries/Carriers | Change Request 1232: Draft Transmittal: "A More Accurate Source of Average Wholesale Price Data (Attached) in Pricing Drugs and Biologicals Covered by the Medicare Program." | Department of Health and Human services, Health Care Financing Administration | | | | | DP Deliberative Process |
| HHC901-07290735 | 2000 or 2001 | Draft Program Memorandum with Attachment | Draft of Memorandum to Intermediaries/Carriers with handwritten notes -Subject: Another Source of Average Wholesale Price data (Attached) in Pricing Drugs and Biologicals Covered by the Medicare program. Related to AB-00-86. (Change Request No. 1232) | HCFA | | | | | DP Deliberative Process |
| HHC901-07590762 | 2000 or 2001 | Draft Program Memorandum with Attachments | Intermediaries/Carriers - Change Request 1232 re "Another Source of Average Wholesale Pricing Data (Attached) in Pricing Drugs and Biologicals Covered by the Medicare Program" | HCFA | | | | | DP Deliberative Process |
| HHC901-07670767 | XX/XX/XXXX | List | Wholesaler Contact Information and Calculations. Handwritten notes regarding Albuterol. Other notes calculating the percentage of spread. | | | | | | DP Deliberative Process |
| HHC901-07840787 | XX/XX/XXXX | Notes | Re Contract Money and Development of AWP Data (Handwritten) | | | | | | DP Deliberative Process |
| HHC901-07880789 | XX/XX/XXXX | Memo-Options Memo | Outlining current policy and options re: Dealing with problems and issues arising from use of DOJ AWP data. | | | | | Niemann, R | DP Deliberative Process |
| HHC901-07900795 | XX/XX/XXXX | Draft Program Memorandum | Intermediaries/Carriers - Change Request 1232 re "Another Source of Average Wholesale Pricing Data (Attached) in Pricing Drugs and Biologicals Covered by the Medicare Program (Draft) | | | | | | DP Deliberative Process |

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| HHC901-08210822 | XX/XX/XXXX | Notes | AWP Prices and Investigation meeting notes (Handwritten) | | | | | | DP Deliberative Process |
| HHC901-08290829 | XX/XX/XXXX | Notes | AWP Prices and Investigation meeting notes (Handwritten). Discussion of using DOJ AWP data. | | | | | | DP Deliberative Process |
| HHC901-08350835 (Notes redacted) | 04/9/1997 | Email | re: carrier payment policy for Self-Injected Lupron | Niemann, Robert | | McCann, Burt | | | DP Deliberative Process |
| HHC901-08360838 | XX/XX/XXXX | Note | Note to Bob Niemann re Clearance of Lupron Language. Legal advice on revising response regarding payment for Lupron and Zolodex and local medical review policy. | Carp, Leila, DHHS/OS | | Neumann, Bob, HCFA | | | AC Attorney-Client, DP Deliberative Process |
| HHC901-08390839 (Portions redacted) | 10/24/1996 | Email | Addressing South Carolina carrier least costly alternative policy regarding Lupron and Zolodex | Schumaker, Bernadette | | Ault, T | | Niemann, R.; Bagley, G.; Primack, A. | DP Deliberative Process, AC Attorney-Client |
| HHC901-08400840 (Last 3 paragraphs redacted) | 12/19/1996 | Email | Discussion after meeting with Hogan & Hartson about payment for Lupron and Zolodex. | Ault, T | | Schumaker, B.; Niemann, R., Bagley, G. | | McCann, B., Wynn, B., Sheingold S. | DP Deliberative Process |
| HHC901-08430844 | 02/26/1997 | Email | With a handwritten notes discussing concerns re: Local Medical Review Policy 97-01-D, Luteneinzing Hormone-releasing Hormone Analogs. Also contains discussion of payment for Lupron and Zolodex. | Sheridan, David | | Neumann, R | | | DP Deliberative Process |
| HHC901-08460848 | 11/24/1998 | Draft | Draft Lupron Statement, by G.N. Rogan, MD, NHIC. Discussing proposed local medical review policy for Lupron and Zolodex. | Rogan, G. N. | | | | | DP Deliberative Process |
| HHC901-08620864 | 02/28/1997 | Draft Letter | Local Medical Review Policy 97-01-D, Luteneinzing Hormone-releasing Hormone Analogs. Discussing reasons for local medical review policy. | Sheridan, David, Medicare Palmetto Government Benefits Administrators | Medical Director | Hulecki, Steven, South Carolina Urology Association | Medical Director | | DP Deliberative Process |
| HHC901-08710873 | XX/XX/XXXX | Slides | Printout of slides entitled "Least costly alternative policy making" Appears to be draft slides. Also discusses payment for Lupron and Zolodex. | Sheridan, David, Palmetto GBA | | | | | DP Deliberative Process |
| HHC901-08740876 | 04/3/1997 | Memo | Note to Bob Niemann re Clearance of Lupron Language. Legal advice on revising response regarding payment for Lupron and Zolodex and local medical review policy. | Carp, Leila, | Attorney, OGC | Neiman, Bob, HCFA | | | AC Attorney-Client, DP Deliberative Process |
| HHC901-08710877 | 05/6/1997 | Email | Discussing comparison between Lupron and Zolodex. | Fourcroy, Jean FDA | | Conrad, Constance, HCFA | | | DP Deliberative Process |

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| HHC901-08780878 (Portions Redacted) | XX/XX/XXXX | Information Sheet | TAC Information Sheet with handwritten notes re Limiting the Payment Allowance of Lupron to that of Zoladex | | | Nieman, Robert,; DACS: OPACP; BPD | | Zone, Bob; Sharpe, John | DP Deliberative Process |
| HHC901-09400943 (941: Release with redactions, 942-43: Released) | 06/30/1996 | Email | Lupron Technology Advisory Committee (TAC) Agenda Item - Reply. E-mail contains discussion of TAC agenda. | Barton, Mccann | | Niemann, R. | | | DP Deliberative Process |
| HHC901-09440945 (944: Released) | Feb. 1993 | Meeting Notes | TAC Meeting Minutes discussing policy regarding payment for Lupron | McCann, Barton | | Niemann, R. | | | DP Deliberative Process |
| HHC901-09460949 | 06/25/1996 | Email with Attachments | TAC Meeting Minutes discussing policy regarding payment for Lupron | Conrad, Constance | | Niemann, R. | | | DP Deliberative Process |
| HHC901-09500950 | 01/2/1997 | Email | Payment For Lupron. Discussing how to instruct carriers regarding payment for drugs. | Niemann, Robert | | Francis, S. | | Ault,; Wynn, B.; Schumaker, B. | DP Deliberative Process |
| HHC901-09510951 | 12/31/1996 | Email | Payment For Lupron. Discussing carriers calculation of estimated acquisition cost. | Jaye, Robert, DHHS/OS | | Ault, T. | | Francis, S. | AC Attorney-Client, DP Deliberative Process |
| HHC901-09530955 | 04/27/1999 | Fax Transmission | Providing list of drugs surveyed for wholesale prices. | Riordan, Mary E. | | Niemann, Bob | HCFA | | DP Deliberative Process |
| HHC901-09730975 | XX/XX/XXXX | Draft Memo | Draft Options paper regarding problems with implementation of Wholesale Prices provided by DOJ. (Draft with Handwritten Notes) | | Director, Center For Health Plans and Providers | The Administrator | | The Deputy Administrator | DP Deliberative Process |
| HHC901-09940994 | XX/XX/XXXX | Note | Explaining question as to use of AWP maintained in FDB. | | | | | | DP Deliberative Process |
| HHC901-09950995 | XX/XX/XXXX | List | Discussion of Concerns with Using Department Of Justice / First Data bank(FDB) Data in Medicare. | | | | | | DP Deliberative Process |
| HHC901-09970997 | XX/XX/XXXX | Note | Discussion of information to be included in letter and policy paper. Discusses use of DOJ data. | | | | | Reed, Cindy | DP Deliberative Process |
| HHC901-10031007 | XX/XX/XXXX | Draft Contract Document | Statement of Work (Medicare Part B Drug Pricing Consistency Methodology and NDC Functionality Development) | | | | | | DP Deliberative Process |
| HHC901-10081013 | XX/XX/XXXX | Draft Contract Document | Task Order Statement of Work (SOW): Medicare Drugs and Biologicals Pricing Consistency Project | | | | | | DP Deliberative Process |

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| HHC901-10141014 | XX/XX/XXXX | Note | Discussion of using alternative data for calculation of AWP. | | | | | | DP Deliberative Process |
| HHC901-10161016 | XX/XX/XXXX | Note | Handwritten notes discussing the use of alternative data for calculation of AWP. | | | | | Reed, Cindy | DP Deliberative Process |
| HHC901-10181028 | 02/3/1999 | Fax with Attachments | First Data Bank Statement Proposal, Government Draft Response and Comments re FDB Price Reports and Threatened Litigation | Stephens, Reed, Department of Justice | | Neimann, Bob | | Riordan, Mary, HHS/OIG | DP Deliberative Process |
| HHC901-10291032 | 05/4/1999 | Fax with Attachments | Revised Version of First Databank Proposal | Riordan, Mary, DHHS/OIG | | Neimann, Bob HCFA; Reed, Larry, HCFA | | | DP Deliberative Process |
| HHC902-00010004 | XX/XX/XXXX | Draft proposal | Discussion of alternative reimbursement mechanisms for the Medicare Program's payment for drugs, and the pros and cons of such policies. (See also HHC902-00190034, HHC902-00350052, HHC902-00810085) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-00050016 | 12/6/1995 | Draft proposal | Discussion of an alternative reimbursement mechanism for the Medicare Program's payment for drugs. | N/A | | N/A | (AWP) | | DP Deliberative Process |
| HHC902-00170018 | 04/1/1996 | Memo | Outline of issues to be discussed at upcoming principal's meeting. Includes discussion of pros and cons of alternative reimbursement mechanisms. | Greenberg, George, ASPE | | Boyd, Anna, Exec Sec | | | DP Deliberative Process |
| HHC902-00190034 | 04/24/1996 | Note with Attachments | Legal Note to Barbara Chanoski regarding a discussion of alternative reimbursement mechanisms. That discussion is attached and contains Leila Carp's handwritten comments on the discussion. (See also HHC902-00010004, HHC902-00350052, HHC902-00810085) | Leila Carp | OGC | Barbara Chanoski | | | DP Deliberative Process, AC Attorney-Client |

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| HHC902-00350052 | 04/29/1996 | Draft NPRM | Draft NPRM (BPD852PB.B, pp. B12-B29) on drug and biological pricing policy. Discusses alternative reimbursement mechanisms and the pros and cons of such policies. (See also HHC902-00010004, HHC902-00190034, HHC902-00810085) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-00530055 | 04/26/1996 | Draft NPRM | Draft NPRM (BPD852PC.C, pp. C9-C11) on drug and biological pricing policy. Discusses potential affects of alternative reimbursement mechanisms. | N/A | | N/A | | | DP Deliberative Process |
| HHC902-00590062 | 02/20/1996 | Briefing Material | Briefing material for the Administrator discussing proposals, pros/cons and potential effects of changes in the following policies: independent physiological labs - physician supervision of diagnostic test, physician fee schedule payment areas, and alternative reimbursement mechanisms. | Administrator | | N/A | | | DP Deliberative Process |
| HHC902-00670067 | 1999-2001 | Note | Note regarding revised drug language in revised draft Fraud and Abuse bill. Contains two comments from Mr. Burney regarding language contained in the draft bill. | Burney, Ira | CMS OL | Nelson, Thayer | OGC | | DP Deliberative Process/ AC Attorney-Client |
| HHC902-00680079 | 05/6/1998 | Memo with Attachments | Mr. Burney's comments on a physician NPRM and private contracts. Also contains Mr. Burney's comments on a transmittal memo to the Secretary and a list of typos. | Burney, Ira | CMS OL | Chanoski, B: Kay, T. | | | DP Deliberative Process |
| HHC902-00800080 (Portions redacted) | 04/22/1998 | Memo w/ handwritten notes | Memo regarding a story on ABC Evening News regarding the quality of compounded drugs dispensed and payment differences for prescription drugs between Medicare beneficiaries and other health care consumers. Contains Mr. Price's suggestion of how to respond to the news story. | Price, William | | Peacock, C. | | Johnson, R.; Proctor, J.: Ruiz, L.: Delillo: Joel K: Walt: Bill L: Bob N | DP Deliberative Process |

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| HHC902-00810085 | 03/12/1996 | Draft | Discussion of alternative reimbursement mechanisms for the Medicare Program's payment for drugs, and the pros and cons of such policies. Contains handwritten comments and corrections from Mr. Spalding. (See also HHC902-00010004, HHC902-00190034, HHC902-00350052) | Spalding, Charlie | | | | | DP Deliberative Process |
| HHC902-00860093 | 03/07/XXXX | Note with attachment of drug pricing NPRM draft | Handwritten note to "Charlie" from Mr. Niemann requesting "Charlie's" comments on the attached drug pricing NPRM draft. Contains discussion of alternative reimbursement mechanisms and the potential impact of such new policies. Draft NPRM contains "Charlie's" handwritten comments on the language. | Niemann, Robert | | Charlie | | | DP Deliberative Process |
| HHC902-00940097 | 12/13/1995 | Memo with Attachment | Memo regarding an upcoming meeting. Attachments contain talking points regarding alternative Medicare Part B reimbursement mechanisms and the pros/cons/potential impact of each. Also attached are talking points for waste/spoilage concerns for chemotherapy drugs. (See also HHC902-01000102, HHC902-01030104) | Bernadette | | Spalding, Charlie; Pat; Bob; Dorothy | | | DP Deliberative Process |
| HHC902-00980099 | 03/22/1996 | Note | Note containing the OGC's opinion regarding the use of data in alternative reimbursement mechanisms. | Salhus, Mary | OGC | Niemann, Robert | | Carp, Leila | AC Attorney-Client, DP Deliberative Process |
| HHC902-01000102 | 12/11/1995 | Draft | Discussion of alternative Medicare Part B reimbursement mechanisms and pros/cons/potential impact of each. Also contains talking points regarding waste and spoilage concerns for chemotherapy drugs. (See also HHC902-00940097, HHC902-01030104) | Niemann, Robert | | | | | DP Deliberative Process |

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| HHC902-01030104 | 12/11/1995 | Draft | Discussion of alternative Medicare Part B reimbursement mechanisms and pros/cons/potential impact of each. (See also HHC902-00940097, HHC902-01000102) | Niemann, Robert | | | | | DP Deliberative Process |
| HHC902-01050106 | 01/29/1996 | Draft | Discussion of alternative Medicare Part B reimbursement mechanisms and pros/cons/potential impact of each. | Niemann, Robert | | | | | DP Deliberative Process |
| HHC902-01070108 | 05/8/1996 | Note | Note containing comments in response to reviewing a draft NPRM regarding alternative reimbursement mechanisms. | Chang, Debbie | Director, OLIGA | Brown, Sue | | | DP Deliberative Process |
| HHC902-01090111 | 6/30/1993 | Draft Memo | Instructions regarding how to determine the acquisition cost of drugs pursuant to 42 CFR 405.517. (See also HHC902-01290131) | | | All ARAs For Medicare | | | DP Deliberative Process |
| HHC902-01120112 | 02/18/1993 | Memo | Comments regarding a draft memorandum from the Administrator to the OIG regarding the OIG report "Physicians' Costs for Chemotherapy Drugs." (See also HHC902-01140115, HHC902-01190119, HHC902-01850185, HHC902-01860186) | Buto, Kathleen, HCFA | | Stojak, Mary, Office of Budget and Administration | | Weintraub, S: Shelby | DP Deliberative Process |
| HHC902-01140115 | 1992-1993 | Memo | Draft Response to OIG Final Management Advisory Report "Physicians' Costs for Chemotherapy Drugs." Provides comments on OIG's findings. (See also HHC902-01120112, HHC902-01190119, HHC902-01850185, HHC902-01860186) | Toby, William | Acting Director, HCFA | Mitchell, Bryan, | Principal Deputy Inspector General, OIG | | DP Deliberative Process |

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| HHC902-01190119 | 01/13/1993 | Memo | Reiterates HCFA response to OIG Final Management Advisory Report "Physicians' Costs for Chemotherapy Drugs." Provides comments on OIG's findings. (See also HHC902-01120112, HHC902-01140115, HHC902-01850185, HHC902-01860186) | Buto, Kathleen, HCFA | Director, Bureau of Policy Development | Director | Office of Budget and Administration | | DP Deliberative Process |
| HHC902-01280131 | XX/XX/XXXX | Draft Memo | Draft of instructions regarding how to determine the acquisition cost of drugs pursuant to 42 CFR 405.517. (See also HHC902-01090111) | | | All ARAs For Medicare | | | DP Deliberative Process |
| HHC902-01850185 | 02/12/1993 | Draft Note | FQA-541. Comments regarding draft memorandum from HCFA administrator to the OIG regarding the OIG Report "Physicians' Costs for Chemotherapy Drugs." | Buto, Kathleen; HHS | | Stajak, Mary | Office of Budget and Administration | Weintraub, S; Rolanda | DP Deliberative Process |
| HHC902-01860186 | 02/9/1993 | Draft Note | Comments regarding draft memorandum from HCFA administrator to the OIG regarding the OIG Report "Physicians' Costs for Chemotherapy Drugs." (See also HHC902-01120112, HHC902-01140115, HHC902-01190119, HHC902-01850185) | Buto, Kathleen | | Stajak, Mary | OBA | | DP Deliberative Process |
| HHC902-01870201 | 2001-2002 | List with Attachments | Discussion of numerous alternative reimbursement mechanisms for Medicare-covered drugs. Includes handwritten notes listing and describing many of the possible alternative reimbursement mechanisms (i.e., brainstorming material.) | Greenburg, Alan | | | | | DP Deliberative Process |

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| HHC902-02140244 | 04/1999 - 06/1999 | Memo with Attachments | Discussion of the issue regarding alternative reimbursement mechanisms and the use of DOJ data regarding one such alternative. Presents an impact analysis of changes in reimbursement and its potential effect on the delivery of care. Includes different documents, including a memo, handwritten notes and charts. (See also HHC902-02510258) | Hash, Michael | Deputy Administrator | Thurm, Kevin | Deputy Secretary | ES; COS | DP Deliberative Process |
| HHC902-02510258 | 04/1999 - 06/1999 | Memo | Discussion of the issue regarding alternative reimbursement mechanisms and the use of DOJ data regarding one such alternative. Presents an impact analysis of changes in reimbursement and its potential effect on the delivery of care. (See also HHC902-02140244) | Hash, Michael | Deputy Administrator | Thurm, Kevin | Deputy Secretary | ES; COS | DP Deliberative Process |
| HHC902-02710310 | 1997-1998 | Draft Memoranda, Email, Handwritten Notes | Series of drafts, notes and emails discussing the pros and cons of an alternative reimbursement mechanism. | Niemann, Robert; Buto, Kathleen; Schumaker, Bernadette | | Schumaker, Bernadette; Wynn, B. | | | DP Deliberative Process |
| HHC902-03150315 | 05/XX/1997 | Stickie/Note | Handwritten note regarding drafting of future legislation or regulations concerning payment for drugs. | Bart | | Niemann, Bob | | | DP Deliberative Process |
| HHC902-03210321 | 11/6/1996 | Letter | Letter regarding Medicare payment for Zoladex and general discussion of Medicare's current reimbursement policy. | Crusick, Elizabeth | Director Office of Physician and Ambulatory Care Policy | Niemann, R. | | | DP Deliberative Process |
| HHC902-03360338 (Portions redacted on 338) | Pre-2002 | Information Sheet w/ Handwritten Notes | Discussion of current policy and potential changes in the policy regarding Medicare coverage of Lupron and Zoladex. | Niemann, Robert; Zone, Bob | Technology Advisory Committee | | | | DP Deliberative Process |
| HHC902-03470351 | 2/13/1998 | Email of Draft Policy w/ Handwritten Notes | Discusses an alternative reimbursement mechanism and lists citations of regulations and statutes that would be affected by implementation of such an alternative. | Bard(?) | | Niemann, Bob | | | DP Deliberative Process |

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| HHC902-03550360 | 10/20/1998 | Draft Final Rule w/ Handwritten Notes | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03610368, HHC902-03760381) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-03610368 | 09/24/1998 | Draft Final Rule | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03550360, HHC902-03760381) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-03690369 | 01/30/1998 | Memo | Note discussing definition of "brand" name for drug. | Marvin | | Niemann, Bob | | | DP Deliberative Process |
| HHC902-03700375 | XX/XX/XXXX | Draft Responses to NPRM Comments w/ Handwritten Comments | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03920395, HHC902-04320437) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-03760381 | XX/XX/1998 | Draft Final Rule w/ Handwritten Notes | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03550360, HHC902-03610368) | Regulatory Staff | | N/A | | | DP Deliberative Process |
| HHC902-03820388 | 08/28/1998 | Briefing Paper | Discussion of numerous non-practice expense issues in the final Physician Fee Schedule regulation. Includes discussion of issues and staff recommendations of how to proceed. Includes draft language of HCFA response to public comments on applicable NPRM. | | | | | | DP Deliberative Process |
| HHC902-03920395 | XX/XX/XXXX | Draft Responses to NPRM Comments w/ Electronic Notes | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03700375, HHC902-04320437) | N/A | | N/A | | | DP Deliberative Process |

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| HHC902-04320437 | XX/XX/XXXX | Draft Responses to NPRM Comments w/ Handwritten Notes | Draft of preamble to final rule. Includes discussion of NPRM previously issued implementing the BBA. Includes responses to the comments received during the comment period. (See HHC902-03700375, HHC902-03920395) | N/A | | N/A | | | DP Deliberative Process |
| HHC902-05150517 | 04/17/1991 | Memo | Memo in response to inquiry from Ms. Nye regarding the legal options for altering the coverage of services provided with the drug Clozaril. (See HHC902-05300531, HHC902-05350535) | Salhus, Mary, HHS/OGC | Attorney | Nye, Christine, HHS/CMS | Director Medicaid Bureau | | AC Attorney-Client, DP Deliberative Process |
| HHC902-05260529 | 06/5/1991 | Memo and Background Materials | Memo discussing upcoming speech to the Drug Information Association. Attached are the main points from Rozann Abato's speech. | Hickman, William, HHS/HCFA | | Kahn, Mike | | | DP Deliberative Process |
| HHC902-05300531 | 03/18/1992 | Memo with Attachment | Memo and draft instructions clarifying the coverage and reimbursement procedures for phlebotomy and case management type services associated with the drug Clozaril. (See HHC902-05150517, HHC902-05350535) | Hickman, William, HHS/HCFA | Director Office of Medicaid Policy | Office of Intergovernmental Affairs: Office of Issuances: Office of Medicaid Management: Office of the General Counsel: Bureau of Policy Development: Division of Medicaid Eligibility Policy; Office of Budget Administration | | | DP Deliberative Process |
| HHC902-05320532 | 03/5/1992 | Handwritten Memo | Short response stating that the author agrees with "the changes" regarding coverage and reimbursement procedures for phlebotomy. | B.A. or B.L. (?) | | Linda | | | DP Deliberative Process |

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| HHC902-05350535 | Late 1991 - Early 1992 | Routing Slip | Mostly handwritten notes listing the names of persons who reviewed SSM Part 4, Section 4580 changes and what changes were made to the document. (See HHC902-05150517, HHC902-05300531) | Joe Dulany | | | | | DP Deliberative Process |
| HHC902-05390540 | 09/5/1990 | Memo | Memo in response to request for consultation by the Region IV Associate Regional Administrator, Division of Medicaid regarding a letter from the state of South Carolina regarding Clozaril. | Hickman, Bill HCFA | Director Office of Medicaid Policy | Associate Regional Administrator, Region IV, Atlanta | Division of Medicaid | Regional Administrator, Office of Field Operations; Office of Medicaid Management | DP Deliberative Process |
| HHC902-05410542 | 06/29/1990 | Memo | Memo in response to request for consultation by the Region V Administrator, Division of Medicaid regarding review of a draft letter from the state of Minnesota to an individual concerning reimbursement for Clozaril. | Abato, Rozann, HHS/HCFA | Acting Director Medicaid Bureau | Regional Administrator, Region V, Chicago | Division of Medicaid | Regional Administrators ; Pete Rodler; Bob Nakielny | DP Deliberative Process |
| HHC902-05430544 | 05/8/1992 | Memo | Memo requesting review and advice regarding Michigan's proposed program to distribute pharmaceuticals to Medicaid recipients through the mail. | DuPre, David, Region V HCFA | Chief, Medicaid Operations Branch Division of Medicaid | Medicaid Bureau/Office of Medical Policy | Medicaid Bureau, Office of Medicaid Policy | | DP Deliberative Process |
| HHC902-05450547 | 02/19/1993 | Memo | Response to memo regarding Medicaid Bureau's response to the Philadelphia Regional Office concerning Pennsylvania's proposal to contract with one pharmaceutical company to provide prescriptions by mail. Discusses The Medicaid Bureau's response and the applicable law the Regional Office must consider when evaluating this policy. | Abato, Rozann, HHS/HCFA | Acting Director Medicaid Bureau | Division of Medicaid Region II, New York | Associate Regional Administrator | Regional Administrators : Boston, New York, Philadelphia, Atlanta, Chicago, Dallas, Kansas City, Denver, San Francisco, Seattle | DP Deliberative Process |

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| HHC902-05630573 | 02/28/1991 | Draft Memo with Attachments | Draft letter in response to congressional inquiry from James L. Oberstar's regarding a constituents question about a potential appeal process to contest reimbursement for purchase of brand name drugs. Discussed the applicable law and advised Congressman Oberstar of how to inform his constituent. [See HHC902-11351140] | N/A | | N/A | | Sizelove, Linda | DP Deliberative Process |
| HHC902-06460651 (Released 649) | 06/28/1990 | Memorandum with Attachments | Memorandum in response to request for clarification of HCFA policy relating to Estimated Acquisition Cost (EAC) and rebates from manufacturers. Memo clarifies the language in the regulation in light of the requesting party's initial understanding. | Abato, Rozann, DHHS/ Medicaid Bureau | Acting Director | Associate Regional Administrator, Region II | | Rodler, Pete | DP Deliberative Process |
| HHC902-06680668 | 06/24/1992 | Note | Response to request for policy clarification on Tennessee's interpretation of usual and customary charges as applied to outpatient drug reimbursement. Cites the relevant regulatory language and clarifies the Tennessee policy in question. | Salhus, Mary, DHHS/OGC | | Nye, Christine | | | AC Attorney-Client, DP Deliberative Process |
| HHC902-06690670 | 03/5/1992 | Note | Response to request for comments regarding a letter from the Associate Regional Administrator in Kansas City requesting clarification as to whether the State of Nebraska may lower dispensing fees of individual pharmacists who agree to accept a dispensing fee from an HMO or private insurance company which is lower than the state dispensing fee. Cites the applicable statutes and regulations pertinent to resolving this issue, and explains OGC's advice. | Salhus, Mary, HHS/OGC | | Reed, Larry | | | DP Deliberative Process |
| HHC902-07040706 | 07/9/1993 | Memo and Attachments | Notifies about Medicaid drug federal upper limit changes. Attachments details the MNPPB assignments and explains what changes were made. | Hickman, Bill | | | | | DP Deliberative Process |

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| HHC902-07150720 | XX/XX/XXXX | Draft Letter (2 copies) | Request for additional or clarifying information regarding an amendment to the Arkansas Medicaid State Plan submitted under Transmittal No. 91-24 which revises the reimbursement methodology for prescribed drugs. Explains the specific line items that need additional or clarifying information, and states that the amendment cannot be fully processed until that information is received. | Hearn, Don, Program Operations Branch | Chief | Whitlock, Kenny, Arkansas Department of Human Services | Deputy Director | | DP Deliberative Process |
| HHC902-07950800 | mid-1997 | Draft Memo w/ Attachments | Provides background on and transmits HHS report to Congress on the average wholesale price of drugs as mandated by Section 4556 of the Balanced Budget Act of 1997. Attachments include draft letters to various members of Congress introducing the report. | Min DeParle, Nancy-Ann | The Administrator, HCFA | Shalala, Donna | Secretary, HHS | | DP Deliberative Process |
| HHC902-08200830 | 4/21/1992 | Memo with Attachment | Memo and attached copy of a proposed response to a regional office regarding durational limits on the number of prescription drugs provided to residents of intermediate care facilities for the mentally retarded. Proposed response offers advice in accordance with the applicable regulations. | Nye, Christine | Director, Medicaid Bureau | Jaye, Bob DHHS/OGC | | Dulaney, Joe | AC Attorney-Client,DP Deliberative Process |
| HHC902-08430843 | 03/15/1994 | Note | Response to Ms. Chambers regarding her questions about HMO reimbursement rates. Provides two comments regarding the suggested interpretation of the applicable regulatory language. | Salhus, Mary, HHS/OGC | | Gaston, Sue, HCFA | | | AC Attorney-Client |
| HHC902-08470848 | 02/18/1999 | Form with Attachment | Form entitled "Center for Medicaid & State Oper Control." Contains handwritten notes as to who reviewed the issue of clarifying HCFA policy regarding dispensing physicians. Attachment is an email note from Pamela Luce to S. Gaston regarding the status of this inquiry. | Lenz, Thomas | | CMSO | FCHP | | DP Deliberative Process |

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| HHC902-08490849 | 01/29/1999 | Memo | Response to request for clarification of HCFA policy regarding dispensing physicians. The note refers to an attachment not presently appended with this document. | Lenz, Thomas HCFA, Kansas City | Associate Regional Administrator for Medicaid State Operations | Richardson, Sally, HCFA | Director, Center for Medicaid and State Operations | | DP Deliberative Process |
| HHC902-08530854 | 08/3/1996 | Note | Response to inquiry regarding a complaint from the National Association of Retail Druggists and the National Association of Chain Drug Stores regarding new federal upper limits and reduced existing federal upper limits. | Aibel, Dan, HHS/OGC | | Grinstead, Darrel | | | AC Attorney-Client, DP Deliberative Process |
| HHC902-08550860 | 7/15/1993 | Form with Attachments | Form entitled Office of Executive Operations Control 930614-0114 regarding a new requirement for Medicaid reimbursement for a brand-name drug. Form includes the names of those who reviewed or worked on this issue and the date on which they received the assignment. Contains two attachments. First is a letter from Bruce Vladeck, Administrator, to M. West, Executive Vice President of the National Association of Retail Druggists responding to the latter's concern regarding a HCFA policy to reduce drug payments to pharmacies. The second attachment is a letter from Bruce Vladeck, Administrator, to Ronald Ziegler, President & CEO of the National Association of Chain Drug Stores similarly responding to the latter's concern regarding a HCFA policy to reduce drug payments to pharmacies. | Ziegler, Ronald | | MB; OMP | | | DP Deliberative Process |

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| HHC902-08750877 | 02/1/1993 | Memorandum | Request for additional information on various unresolved issues following a teleconference with state pharmacists regarding the federal upper limit list. Attachment is a list of 18 drugs and the corresponding federal upper limit, AWP unit cost, NE unit cost, unit rebate and net unit cost for each. | Abato, Rozann, HCFA | Acting Director, Medicaid Bureau | Associate Regional Administrator, Division of Medicaid, Kansas City | | Regional Administrator Kansas City; Rodler, Pete; Reed; Abato, Rozann | DP Deliberative Process |
| HHC902-10051006 | 06/9/1987 | Briefing Notes | Briefing notes regarding a final rule establishing two uniform but separate upper limits for states irrespective of the payment system they choose to utilize. Provides basic information regarding the purpose and projected effects of the final rule. | Lovechoi, T. | | | | | DP Deliberative Process |
| HHC902-10071010 (Released 1008-1010) | 10/20/1987 | Notes with Attachment | Debriefing of the October 14, 1987 meeting between HCFA and the Joint Commission of Pharmacy Practitioners (JCPP) regarding the implementation of changes to federal upper limits on payment for prescription drugs. Discussed the primary form and topics of the meeting, and listed an outstanding issue. | Lovechoi, Anthony | | | | | DP Deliberative Process |
| HHC902-10111061 | 08/10/1987 | Memo with Attachment | Memo clearing the draft of a new regulation regarding specific upper limits for multiple source and other drugs (Part VI, Section 6305) in the Medicaid Manual. Attachment is the draft regulation itself. | Streimer, Robert; Buro, Kathy, HFCA | Director, Bureau of Eligibility, Reimbursement and Coverage | Director, Office of Issuances, OEO | | | DP Deliberative Process |

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| HHC902-10621067 | 08/00/1987 | Article | Draft of an article by Don Newman entitled "Drug Topics." Specifically, the draft article addresses the new federal upper limits for payment of prescription drugs. The draft article discusses the overall goals of Medicare policy, the old regulations, and the new regulations. Handwritten comments and corrections appear on the draft article. | Newman, Don, DHHS; Shosky, John, DHHS, IOS Public Affairs | Under Secretary | Lovecchio, Tony, HCFA | | | DP Deliberative Process |
| HHC902-10681070 | 1987-1988? | Memo | Memo regarding Mr. Lovecchio's letter to all state Medicaid directors concerning payment for schedule II drugs and suggesting how the letter should be modified. | Steinhouse, Edward, DHHS/OGC; | Deputy Chief Counsel | Lovecchio, Tony, DHHS/ OGC | Director, Division of Alternative Reimbursement Systems | | DP Deliberative Process, AC Attorney-Client |
| HHC902-10711071 | 1987-1988? | Letter - draft | Proposed text of a letter to be sent to state Medicaid directors from Bill Roper to clarify two issues in Medicaid drug reimbursement. Specifically, the draft letter clarifies questions regarding the inclusion of certain drugs in a new published final rule on the payments for drugs under the Medicaid program. | Roper, William, HCFA | Administrator | | State Medicaid Directors | | DP Deliberative Process |
| HHC902-10781089 | 09/28/1987 | Speech | Draft of speech titled "The Complicated History of Medicaid Regulations on Drug Reimbursement." Discussion of regulations from 1975 to 1987. Discusses Dr. Helms' assessment of the new final rule. | Helms, Robert B. | Assistant Secretary For Planning and Evaluation | | | | DP Deliberative Process |

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| HHC902-10901096 | 04/1/1988 | Memo with Attachments | Memo provides comments following review of Arkansas Medicaid State Plan Amendment 88-05 in response to Region VI's request. Attachments include Region VI's original request for review and comments on the Arkansas SPA, and a draft letter with handwritten notes from the State Operations Branch to the Deputy Director of the Arkansas Department of Human Services Division of Economic and Medical Services requesting additional or clarifying information regarding the Arkansas SPA. | Booth, Charles, HFCA | Director, Office of Reimbursement Policy | Associate Regional Administrator, Financial Operations, RO VI | | Regional Administrator | DP Deliberative Process |
| HHC902-11051106 (Released 1106) | 11/3/1987 | Draft Letter w/ Attachment | Draft letter in response to a Public Inquiry Request for Assistance from Michael A. Carbone requesting that antibiotics and anticonvulsants be excluded from the new Medicaid rules governing upper limits of payment for certain multiple source drugs deemed therapeutically equivalent by the FDA. | Inquiries Staff | | Office of Reimbursement Policy | | DP Deliberative Process | |
| HHC902-11071107 | 04/13/1988 | Note | Comment to draft OEP response to Region X regarding Oregon Section 1915 (b) Waiver Request (contracting for pharmaceuticals goods and services). Also requests additional information about the waiver request. | Lovecchio, Anthony | | Debbie Helms | Rodler, Peete; Underhill, Jim; Johnson, Bruce | DP Deliberative Process | |
| HHC902-11171117 | 1987-1988? | Draft Letter | Proposed text of a letter to be sent to state Medicaid directors from Bill Roper to clarify two issues in Medicaid drug reimbursement in lieu of the new final rules regarding federal upper limits. | Roper, William, | Administrator | State Medicaid Directors | | DP Deliberative Process | |
| HHC902-11241125 | 1987-1988? | Draft Letter | Formal request for additional information regarding State Plan Amendment 88-3, "Upper Payment Limits for Prescribed Drugs." Includes a detailed list of the information requested. | Shulman, Theodore | Associate Regional Administrator, Division of Program Operations | Perales, Cesar, New York State Department of Social Services | Commissioner | DP Deliberative Process | |

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| HHC902-11351140 (Released 1138-40) | 02/28/1991 | Draft with Attachments | Draft letter in response to congressional inquiry from James L. Oberstar's regarding a constituents question about a potential appeal process to contest reimbursement for purchase of brand name drugs. Discussed the applicable law and advised Congressman Oberstar of how to inform his constituent. Attached is the request for assistance by a Congressional Inquiry. [See HHC902-05630573] | Oberstar, James | | N/A | | Sizelove, Linda; Sciulli, M. | DP Deliberative Process |
| HHC903-00010007 (Released 1, 4, 6-7.) | 07/17/1995 | Letter | Draft Language for use in Response to Senator Max Baucus on Behalf of Dr. Thomas C. Olson; Discussion of payment for drug Bellergal. | Pharmacy team | CMSO | Baucus, Max | Senator | | DP Deliberative Process |
| HHC903-00080022 | 07/11/1994 | Memo with/attached draft OIG report | Subj: Medicare Part B - Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment (DME); Evaluation of policies regarding reimbursement for drugs used with DME, and recommendations to carry forth said policies. | Brown, June Gibbs | Inspector General, HHS | Viadeck, Bruce C. | Administrator, HFCA | | DP Deliberative Process |
| HHC903-00230026 (Released 26) | 9/21/1990 | Letter | Draft language for use in responding to Congressman Jim Burning who wrote on behalf of Mr. Richard E. Murray; Explanation of regulations establishing limits and criteria on FDA evaluated therapeutically equivalent generic drugs. | E. Faulk | Medical Bureau/ HHS | Bunning, Jim | Congressman | | DP Deliberative Process |
| HHC903-00270027 | 07/30/1990 | Note | Discussion of ASPE Comments on Letters to Senator Heinz and Spector regarding aggregate upper limits for drug prices. | Abato, Rozann | HCFA | Executive Sectariat | HCFA | | DP Deliberative Process |
| HHC903-00280028 | 7/26/1990 | Clearance Sheet | Sec Sig to Henry/Spector - Prescription Drugs; reference to ASPE's and Boyd's comments | | | MB | | | DP Deliberative Process |
| HHC903-00290029 | 07/25/1990 | Letter | Heinz Letter on Medicaid Drug Payments; revision requested with additional information | Boyd, Anna for Kerr, Eleanor | | Somsak, Joyce | | | DP Deliberative Process |

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| HHC903-00300034 | 07/19/1990 | Memo w/attached letters | Draft Letters to Senator Heinz and Spector regarding Medicaid prescription drug pricing and aggregate upper limits--Concurrence with Comment; instructions on content of letter and statement of policy on pricing; suggestions on revisions for letter | Gerry, Martin H. | Assistant Secretary For Planning and Evaluation, HHS | Kerr, E. | Executive Secretariat | | DP Deliberative Process |
| HHC903-00350045 (Released 37-45) | 7/12/1990 | Draft letter with attachment | Suggested Language for Response to Senator Thurmond on behalf of his Constituent, John W. McGee, R. PH, regarding the federal Medicaid policy as applied to pharmacies using Average Wholesale Prices under state Medicaid programs | Faulk | Medical Bureau/ HCFA | Senator Thurman | | | DP Deliberative Process |
| HHC903-00460049 | 07/13/1990 | Draft Report | Brief Overview of the Federal Medicaid Prescription Drug Program; states' payment methodologies as applied to multiple source drugs and for all other drugs | Rodler, Pete | Medicaid Bureau | | | | DP Deliberative Process |
| HHC903-00530055 | 04/20/1990 | Short Note | Discussion of whether States are allowing Therapeutic Substitutions for Drugs and the usage of average wholesale prices; approval/disapproval of various state plans | Abato, Rozann | | Wilensky, Gail | | Hickman, Bill | DP Deliberative Process |
| HHC903-00560058 | 07/11/1990 | Memo with attachment | Notifications to States Regarding Drug Items subject to Specific federal Upper Limits (42 CFR 447.332); Discusses process in issuing notices of FDA drug reclassifications modifying upper limits; | Abato, Rozann | Acting Director, Medicaid Bureau | McDonough, Lawrence L. | Region Administrator, Region IX, San Francisco, Division of Medicaid | | DP Deliberative Process |
| HHC903-00590061 | 07/10/1990 | Report | SECBRIEF re: Reimbursement methodologies dealing with a state's determination of "estimated acquisition cost". | Rodler P/Rotter N | | | | | DP Deliberative Process |

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| HHC903-00620065 | 10/7/1993 | Letter | Draft Language to use in response to Representative Christopher Shays on Kwell; DESI review on safety and effectiveness of drugs | Weaver, R | | Shays, Christopher | Congressional Representative | | DP Deliberative Process |
| HHC903-00670070 | 02/25/1994 | Memorandum | Legal basis for a state's request for a refund of Federal Financial Participation (FFP) for Less Than Effective (LTE)/Identical Related or Similar (IRS) drugs | Salhus, Mary | OGC/HCF | | | | AC Attorney-Client, DP Deliberative Process |
| HHC903-00740081 | 02/12/1987 | Note and attachments | Medicaid Drug Payment policy to replace the inactive Maximum Allowable Cost (MAC) program and promote State flexibility in administering Medicaid; | Anthony, C., Ross, Ph.D., HCFA | | The Administrator | | | DP Deliberative Process |
| HHC903-00820083 | 08/9/1987 | Draft Briefing Notes | Limits on Payments for Drugs - Medicaid - Final Rules which would establish uniform but separate upper limit standards for States irrespective of the payment system they choose to utilize | Lovecchio, T. | | | | | DP Deliberative Process |
| HHC903-00840089 | 12/22/1986 | Draft Memo | Overview of the Notice of Proposed Rulemaking (NPRM); discussion of Maximum Allowable Cost (MAC) program, Pharmacists' Incentive Program (PhIP), and Competitive Incentive Program (CIP) | Rodler, Pete | | | | | DP Deliberative Process |
| HHC903-00900090 | XX/XX/XXXX | Short Report | Additional Statement of Policy regarding adoption of a formula approach for setting upper limits for multiple source drugs | | | | | | DP Deliberative Process |
| HHC903-01030110 | 08/11/1988 | Memo | Drug Reimbursement Reform Regulations as applied to Maximum Allowable Cost (MAC) program, Pharmacists' Incentive Program (PhIP), and Competitive Incentive Program (CIP); state plan process | Rodler, Pete | | | | | DP Deliberative Process |

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| HHC903-01110114 | 02/18/1987 | Draft Memo with attached note | Discussion of Medicaid Drug Payment system that States would be required to follow, and of the Maximum Allowable Cost (MAC) program, Pharmacists' Incentive Program (PhIP), and Competitive Incentive Program (CIP). | Roper, William L | Administrator, HCFA | | The Under Secretary, HHS | | DP Deliberative Process |
| HHC903-01180019 | 2/22/1987 | Note | Short note of Medicaid Drug Payment system that States would be required to follow, and of the Maximum Allowable Cost (MAC) program, Pharmacists' Incentive Program (PhIP), and Competitive Incentive Program (CIP). | Anthony, C. Ross, | | | The Administrator, HCFA | | DP Deliberative Process |
| HHC903-01200121 | 12/30/1986 | Short note and handwritten attachment dated 12/29 | Drug Reimbursement in response to a subject memorandum regarding meetings with State Medicaid officials. Purpose of meeting was to obtain feedback grading administrative costs associated with implementation of CIP. | Anthony, C. Ross, | Ph.D., HCFA | Kuzmich, Paula | AAEA | | DP Deliberative Process |
| HHC903-01220124 | 12/22/1986 | Note with attached memo | Report of a meeting convened to discuss the Competitive Incentive Program (CIP) as part of the drug reimbursement policy | Anthony, C. Ross, Ph.D | Associate Administrator for Program Development/HCFA | Streimer, Robert | | | DP Deliberative Process |
| HHC903-01250133 | Approximately 1986. | Note and attachments | Analysis of Medicaid Drug Reimbursement Alternatives; identification of approved drugs for policy limits; state-by-state baseline, and information on drugs and drug volume | Streimer, Robert A | | Boggs, Judy | | | DP Deliberative Process |
| HHC903-01340137 | 12/12/XXXX (either 1986 or 1987) | Memo | Decision on how to proceed with Pharmaceutical Payment Reform for the Medicaid program; summary of the majority of the comments received pursuant to Notice of Proposed Rulemaking | Anthony, C. Ross, Ph.D | Associate Administrator for Program Development | | The Administrator | | DP Deliberative Process |
| HHC903-01390143 | 02/24/1987 | Memo | Final Regulation on Medicaid Prescription Drug Payment Policy; background on the issue of measuring individual state drug payment policies with a recommendation for the final regulation and inclusion of an unresolved issue regarding the monitoring of state compliance | Helms, Bob | | Note To The Under Secretary | | Roper, Bill | DP Deliberative Process |

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| HHC903-01440148 | 08/22/1986 | Note with handwritten notation and attachments | Briefing Materials on Medicaid Prescription Drug Regulations (BERC-356-P) for the State Medical Group (SMG) Meeting September 15, 1986; discussion of proposed rules and their alternatives for comment for the purpose of establishing prescription drug reimbursement methodology | Lovecchio, Tony | | | BERC ES | Booth, Chuck | DP Deliberative Process |
| HHC903-01500154 | 03/6/1987 | Draft Regulation | Draft at a full specification of the final rule, Medicaid Drug Reimbursement, with pointed reference to payment limits for certain drugs | Francis, Walt | HHS/Office of the Secretary | Lovecchio, T | | | DP Deliberative Process |
| HHC903-01550173 | XX/XX/XXXX | Handwritten Draft | Medicaid Drug Reimbursement Reform containing background information from a 1983 task force, drug price competition and patent term extension, and OIG report; also contains Draft Proposed Rules and analysis of alternative programs | | | | | | DP Deliberative Process |
| HHC903-01740174 | 02/4/1987 | Memo | Medicaid Drug Payment Policy: Discussion of establishing Medicaid upper limits for generic drugs. | Anthony, C. R., Ph.D. | Associate Administrator for Program Development, HHS, HCFA | | The Administrator | | DP Deliberative Process |
| HHC903-01750237 | 02/5/1987 | Note and attachment | Detailed analysis of Medicare Prescription Drug Regulation and Medicaid Drug Reimbursement Proposals; recommendation for best choice in view of report and other considerations | Lovecchio, T. | | Booth, Chuck | | | DP Deliberative Process |
| HHC903-02380257 | 01/28/1986 | Report and note dated 01/08/1986 | HCFA Medicaid Prescription Drug Reform; budget data; current policy; regulatory proposals; reinstitution of the MAC program; addendum to specifications of Phip/CIP/MAC regulations; provisions or changes to previously published provisions | Streimer, R. A. | | Kelly, Carol | | | DP Deliberative Process |

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| HHC903-02580326 | 11/21/1984 | Memo | Decision regarding Federal Prescription Drug Enforcement Policies governing reimbursement; presentment of policy options and program changes recommended by the Task Force | Helms, Robert B, Ph.D. | Acting Assistant Secretary for Planning and Evaluation | The Secretary | | | DP Deliberative Process |
| HHC903-03290332 | 4/28/1986 | Note and attachments | HCFA Drug Program - Data Needs and Time Frames for Step Completions, to reestablish current MAC program, to review MAC program to reflect DHHS Task Force recommendations, and to establish PhIP limits | Streimer, Robert | | Boggs, Judy | | | DP Deliberative Process |
| HHC903-03730385 | 2/2/2001 | Summary with attachments | Discussion of TAP litigation and payment for Lupron. | Attachment from Winkler, Susan AUSA | | | | | WP Work Product/ AC Attorney Client |
| HHC903-04580461 | 08/14/1997 | Memo | Significant Activities for the Week Ending August 8, 1997: detailing items of interest, significant activities for the administrator, meetings with particular entities and contact info. Includes discussion of TAP litigation. | Fried, Bruce Merlin | Director, Center For Health Plans and Providers | | The Administrator | | DP Deliberative Process |
| HHC903-05140519 | XX/XX/XXXX | Memo | Requirements for drug Vancomycin infusion; drug coverage and clinical rationale; recommendations for administration; clinical alternatives | Jewell, Kay, MD | | Bonander, Larry; Rutemueller, Walt; Robinson, Chester; Hoyer, Tom | | | DP Deliberative Process |
| HHC903-05200523 | 03/6/1997 | Draft | Coverage issues - Durable Medical Equipment; covered and non-covered indications for treatment using infusion pumps | | | | | | DP Deliberative Process |
| HHC903-05240525 | 05/23/1995 | Short Note | May 18 Meeting with OPTIVITA representatives and their general recommendations regarding Vancomycin and coverage of external infusion on pumps | Jewell, Kay | | Robinson, Chester, Rutemueller; Walt; Bonander, Larry | | | DP Deliberative Process |

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| HHC903-05260537 | 05/24/1995 | Memo | Medicare Coverage of Vancomycin as part of a Durable Medical Equipment (DME) Benefit; background on infusion pumps; discussion of the DMERC medical review policy on external infusion pumps; and options for coverage | Robinson, Chet; Rutmuller, Walter; Bonander, Larry | | Hoyer, Tom | | | DP Deliberative Process |
| HHC903-05380540 | 04/18/1995 | Memo | HCFA reimbursement For Home Use of Vancomycin & CDC Recommendations for Preventing the Spread of Vancomycin Resistance | EIS Officer, IBP, HIP< & NCID (Public Health); Bonander; Robinson, Chet | | | | | DP Deliberative Process |
| HHC903-05430547 | 05/24/1995 | Memo (Revised) | Vancomycin (Coverage Issue); drug requirements and methods for safe infusion of drug; clinical rationale and recommendations for safe administration | Jewell, Kay | MD | Bonander, Larry; Rutmuller, Walt; Robinson, Chester; Hoyer, Tom | | | DP Deliberative Process |
| HHC903-05480555 | 05/23/1995 | Memo | Vancomycin and coverage of external infusion pumps; pump requirements DMERC requirements as applied to beneficiaries with respect to alternate items or pumps | Jewell, Kay | | Robinson, Chester, Rutmuller; Walt; Bonander, Larry | | | DP Deliberative Process |
| HHC903-05560568 | 05/24/1995 | Memo | Vancomycin Coverage of external infusion pumps; pump requirements; DMERC requirements for safe administration; effectiveness of alternate pump | Jewell, Kay | M.D. | Bonander, L; Rutmuller, W.; Robinson, C.; Hoyer, T | | | DP Deliberative Process |
| HHC903-05690573 | XX/XX/XXXX | Draft | Medicare Carrier Manual Re: Coverage Issues; suggested revisions for infusion pumps | Walt | | Sharon | | | DP Deliberative Process |
| HHC903-05740583 | 09/10/1993 | Fax and attachments to Anne Marie Hummell from Sarah Frances | Request for legal Opinion on Coverage of Outpatient Prescription Drugs Used in Conjunction with Durable Medical Equipment | Chase, Lisa | OGC/OIG | Reeb, George M. | Assistant Inspector General for Health Care Financing Audits | Morris, Lewis, Deputy Associate General Counsel | AC Attorney-Client |

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| HHC903-05870594 (Released 593-594) | 10/1/1993 | Draft | Medicare Carrier Manual on Infusion Pumps; covered and non-covered indications for treatment using infusion pumps; letter summarizing salient points in discussion with recommendation for a clarification to the Medicare coverage policy for infusion pumps | Schatz, Gordon S. | Reed, Smith, Shaw & McClay | Hummell, Anne Marie, Director | Division of Medical Services Coverage Policy, HCFA | Wren, Robert E.; Goetzke, Gary A. | DP Deliberative Process |
| HHC903-05950595 | 08/8/1995 | Proposed Criteria | Proposed Criteria for Medicare Coverage of IV Infusion Pump; basic requirement for administration of drug with respect to patient's condition | | | | | | DP Deliberative Process |
| HHC903-05960598 | 05/30/1995 | Fax cover sheet with short attached memo | Usage of Vancomycin CDC's determination of an effect on resistant strains | Oleck, Adrian M., M. D. | Administar Federal | Rutemueller, Walt | | Huges, Paul, M.D.; Zone, Robert M.D., Majors, Elizabeth; | DP Deliberative Process |
| HHC903-05990601 | 10/27/1994 | Memo | Re: OIG Draft Report: " Medicare Part B Reimbursement to Providers for Drugs Used in Conjunction with DME" (a-06-0079); Additional comments refining/furthering concurrence with Administrator's memo | Steinhouse, Edward | | Ault, Tom | | | DP Deliberative Process |
| HHC903-06060640 | 05/11/1990 | Memo and attached report | Response to a request from HCFA to the Public Health Service's Agency for Health Care Policy and Research to conduct an assessment on the safety and clinical effectiveness external insulin infusion pumps for the treatment of diabetes mellitus (Coverage Issue) | Holohan, Thomas V., M.D | Director, Office of Health Technology Assessment | | Director, BPD/HCFA; Clinton, J. Janette, Acting Administrator, AHCPR | | DP Deliberative Process |
| HHC903-06410649 | 04/5/1993 | Note with attached report | Review of issues surrounding current Medicare coverage and payment of services related to Home Drug Infusion Therapy; trends in utilization; overview of questions raised by current policies with some recommendations to approach certain issues; discussion of Medicare reimbursement/current payment methodology (Coverage Issue) | Collins, Dorothy Burk | | Buto, Kathy; Ault, Tom | | Booth, Chuck; Wren, Bob | DP Deliberative Process |
| HHC903-06500650 | 08/14/1996 | E-mail | Coverage of Insulin Infusion Pumps | Hoyer, T. | | Buto, K. | | Ault, T.; Robinson, C.; Feinberg, L. | DP Deliberative Process |

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| HHC903-06530655 | 03/1/1996 | Draft letter | Revised Language for response to Congressman Sam Gejdenson on behalf of Theodore A. Spanos; discussion of infusion pumps, coverage of self-administered drugs and coverage of home health services (Coverage Issue) | | | Siebert, Dennis | | | DP Deliberative Process |
| HHC903-06560657 | 2/26/1996 | Draft Letter | Response to inquiry regarding Medicare Coverage; cancer drugs and treatment; coverage of home health services (Coverage Issue) | Smits, Helen L., MD | Deputy Administrator | Gejdenson, Sam, House of Representatives | The Honorable | | DP Deliberative Process |
| HHC903-06580660 | XX/XX/XXXX | Draft | Medical Carrier Manual on Coverage issues - Durable Medical Equipment 60-14 (handwritten); covered and non-covered indications for treatment using infusion pumps | | | | | | DP Deliberative Process |
| HHC903-06610672 | XX/XX/XXXX | Draft | Clarification of Medicare Coverage Policy for External Infusion Pumps for Insulin with Attached 3/26-27 Minutes; | | | | | | DP Deliberative Process |
| HHC903-06730676 | 08/24/1992 | Draft | Carrier's Proposed Policy on Medicare Coverage of Infusion Therapy (Memorandum from Gene Hyde, Dated May 20, 1991) -- Information on coverage requirements; | Buto, K. | Director, Bureau of Policy Development, HCFA | | Regional Administrator, Kansas City | Tigman, Joe; Hyde, Gene; R. B. | DP Deliberative Process |
| HHC903-06780679 | 09/16/1986 | Memo | Medicare Coverage of Drug Delivery Systems--Assessment of what drug/treatment/device combinations should be focused upon | Buto, K | Acting Deputy Director, Bureau of Eligibility, Reimbursement and Coverage | | Director, Office of Health Technology Assessment | | DP Deliberative Process |
| HHC903-06850698 | 11/12/1991 | Memo and attachments | Coverage of Drugs used with Durable Medical Equipment (responding to Memorandum from Bunnee A. Butterfield, Dated October 4, 1991 re: clarification of coverage policy)-- INFORMATION | Buto, K. | Director, BPD | | Regional Administrator, Seattle; Acting Associate Regional Administrator for Medicare | | DP Deliberative Process |

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| HHC903-06990701 | 08/27/1993 | Memo and attachment | Discussion of audit, "Self-Administered Outpatient Drugs Used with Nebulizers - Medicare Part B" (A-06-92-000790) | Streb, John A. | Director, Management Planning and Analysis Staff, OBA | HCFA | HCFA Leadership | | DP Deliberative Process |
| HHC903-07020710 | 5/19/1993 | Fax transmittal with attachment | Home Health DME Benefit - Coverage of External Infusion Pumps Including Necessary Supplies, Drugs and Biologicals (Draft) | McKeown, Robert A. | Senior Vice President, Medicare operations & Provider Services | | Chief Executive Officers of Home Health Agencies for which Independence Blue cross is Medicare Intermediary | | DP Deliberative Process |
| HHC903-07110720 | 9/9/1993 | Note and attached briefing materials | Briefing Materials for Hearing on Coverage of Home Infusion Therapy, House Energy and Commerce Subcommittee on Oversight and Investigation, September 9, 1993 | Wren, B. | | Zutell, Joyce | | | DP Deliberative Process |
| HHC903-07310732 | 10/18/1993 | Draft HCFA response with handwritten notations | Page 2 of a draft HCFA Response regarding DMERC servicing of the National Supplier Clearinghouse (Coverage Issue) | | | | | Thomas, John | DP Deliberative Process |
| HHC903-07330737 | 11/2/1993 | Memo and drafts | Agency Comments on OIG Final Report, "Medicare Home Infusion Therapy" (OEI-02-92-00420) (Coverage Issue) | Kavanagh, Gary P. | Deputy Director, BPO, HCFA | Attn: Greene, V. | Director, Office of Budget and Administration | Director, OCFM; Director, OMBA | DP Deliberative Process |
| HHC903-07380738 | 11/XX/1993 | Memo | Giving opinion of one component to another component of HCFA regarding OIG Final Report: Medicare Home Infusion Therapy. | Gagel, Barbara J. | Director, Health Standards and Quality Bureau | | Director, Office of Budget and Administration | | DP Deliberative Process |
| HHC903-07390739 | XX/XX/XXXX | Note | OIG Final: Medicare Home Infusion Therapy -- OIG-02-92-00420. A component of HCFA gives its comments on the final OIG report. | Gustafason, Thomas A. | Acting Director, Office of Legislation and Policy | Green, Vicki | | | DP Deliberative Process |
| HHC903-07400748 | 05/8/1995 | Handwritten letter and attachment | January 13, 1995, DMERC Medical Draft Policy for notice and Comment re: External Infusion Pumps (Coverage Issue) | Larry | | Chester | | Walt, Kay | DP Deliberative Process |
| HHC903-08070810 | 03/19/1997 | Draft | Draft language for use in reply to Congressman Ballenger's Inquiry on behalf of David Hardaway, M.D. Discussion of Medicare payment for Zoladex. | Niemann, R. | | Ballenger, Cass | Congressman | | DP Deliberative Process |
| HHC903-08110811 | 04/7/1997 | Draft | Draft language for response to Senator Cinrad'd inquiry on behalf of the concerns of Dr. Patrick Stoy. Discussion of payment for drugs albuterol and itatropium. | | | | | | DP Deliberative Process |
| HHC903-08120812 | XX/XX/XXXX | Revised Language | incorporating revised language and revisions re:Partial Denials language for MCM section 7340. Discussion of coverage of item or service. | Rutemueller, W.; Bonander, L.; Milhorn, Ron; Niemann, B. | | | | | DP Deliberative Process |

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| HHC903-08130821 | 07/29/1997 | Draft | Draft Comments of Different HCFA components re: OIG Draft Report OEI_03-9700290 "Excessive Medicare Payments for Prescription Drugs" | Wynn, Barbara O. | Director, Plan and Provider Purchasing Policy Group, CHPP, HCFA | Management Analysis and Planning Staff, OFHR | | | DP Deliberative Process |
| HHC903-08220825 (Released 823-825) | 06/20/1997 | Draft | Draft language for use in reply to Peggy Haug re: Medicare Reimbursement rates for Lupron and Zoladex | Karplak, Sonya; Nieman B. | | Haug, Peggy | | | DP Deliberative Process |
| HHC903-08350840 (Released 835, 837-840) | 05/2/1996 | Draft | Response to Congressional Inquiry by Karen Thurman regarding payment for Lupron and Zoldex. | Schumaker, B. | | Sheingold, S. | | | DP Deliberative Process |
| HHC903-08410845 (Released 842-45) | 05/3/1996 | Draft | Draft language for reply to Congressman David Mingle re: Medicare Payment for Influenza vaccine | King, Cheryl, Office of Correspondence; Nieman, R. | | Mingle, David | Congressman | | DP Deliberative Process |
| HHC903-08460850 (Released 847-850) | 05/15/1996 | Draft response to citizen's inquiry re: Medicare Payment Policy for Drugs | Draft language for reply to Ronald Grouskey. Discusses how much a provider can charge a beneficiary for drugs. | Shaw, M., Office of Correspondence; Nieman, R. | | Grouskey, Ronald | Congressman | | DP Deliberative Process |
| HHC903-08780883 | 04/11/1988 | Draft | Draft language for use in responding to Congressman Herbert Bateman's inquiry to reimbursement for chemotherapy on a reasonable charge basis. | Hayes, D., Inquiries Staff; Moore, Pat | | Bateman, Herbert H. | Congressman | | DP Deliberative Process |
| HHC903-08840893 | 11/22/1987 | Draft | Draft language for use in response to Senator Howell Heflin's inquiry re: Medicare payments for Estradurin drugs on a reasonable charge basis. | Almquist, Pauline, Inquiries Staff; Moore, Pat | | Heflin, Howell | Senator | | DP Deliberative Process |
| HHC903-08940904 | 03/30/1994 | Email and attachments | discussing how HCFA should interpret and use pricing data to determine AWP | Mirabal, Joe | Reimbursement Specialist, HCFA, New York City | Weintraub, Stanley | HCFACOM | | DP Deliberative Process |
| HHC903-09050911 | 03/22/1994 | Email and attachments | Discussing how to determine acquisition costs of drugs for Medicare reimbursement. | Mirabal, Joe | Reimbursement Specialist, HCFA, NYC | Weintraub, Stanley | HCFACOM | | DP Deliberative Process |
| HHC903-09120912 | 02/25/1994 | Note | Comment on draft instructions for determining acquisition costs of drugs. | Streimer, S. H. | HCFA | Booth, Charles | | | DP Deliberative Process |
| HHC903-09170917 | 04/12/1994 | Memo | comments on AWP calculations re: oncology drugs. Discusses how often they believe AWP data should be updated by regional carriers. | Streimer, S. H. | | Booth, Charles | | | DP Deliberative Process |

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| HHC903-09180930 (Released 918-924) | 7/3/1990 | Memo | Memo discusses HCFA instructions to carriers and intermediaries regarding drug pricing. Recommends approach for instructing carriers in the future regarding payment policy. | MJ Christenberry | Associate Regional Administrator, Dallas Region, Division of Medicare | Kathleen Buto | | | DP Deliberative Process |
| HHC903-09340950 | 2/22/1994 | Memo and attachments | Memos with handwritten notes discussing Lupron expenditures for years 1990 thru 1994 inclusive. Includes other draft memoranda explaining Medicare drug reimbursement. | Booth, Charles, HFCA | Director, Office of Payment Policy | All Associate Regional Administrators for Medicare | | | DP Deliberative Process |
| HHC903-09510953 | 08/12/1992 | Fax cover sheet from John Gradowski to Stan Weintraub dated 10/20/92 with a 2-page memo | Attaching memo re:Calculation of the Average Wholesale Price for Drugs. Discussing carrier suggestions regarding drug pricing. | Benz, Albert | Associate Regional Administrator, Division of Medicare, HCFA, Seattle RO X | | Director, Office of Program Operations Procedures, BPO | | DP Deliberative Process |
| HHC903-09540957 | 01/24/1994 | Draft | Memorandum to all ARAs on Determination of Acquisition Cost of Drugs with handwritten notes | Stan | | Bernie | | | DP Deliberative Process |
| HHC903-09580960 | XX/XX/XXXX | Draft | redlined draft Memorandum to all ARAs on Determination of Acquisition Cost of Drugs | | | All ARAs For Medicare | | | DP Deliberative Process |
| HHC903-09660974 | 2/1/1994 | Draft | Discussing different alternatives to help carriers determine Acquisition Cost of Drugs | | | All ARAs For Medicare | | | DP Deliberative Process |
| HHC903-09750983 | 08/12/1992 | draft | Routing sheet attaching draft proposal from Seattle Ro regarding alternative calculation methods for AWP | Butterfield, Bunnee for Benz, Albert J. | Associate Regional Administrator, Division for Medicare, HCFA, Seattle RO X | | Director, Office of Program Operations Procedures, BPO | | DP Deliberative Process |
| HHC904-00010046 (Released 0008-42) | 04/13/1992 | Memo | Review of Proposed Texas' Disallowance of Medicaid Payment for less than effective drugs. | | | McNally, Dave | | | DP Deliberative Process |

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|---------------------------------------|------------|---|---|---------------------------|---|--------------------------------------|--|---------------------------------------|---|
| HHC904-00470058 | 01/9/1994 | Note w/attachments | Report of contact with Robin Schneider re: potential anti-kickback violation by drug company involving replacement devices to practitioners who treated Medicaid beneficiaries. | Gaston, Sue | | | | | DP Deliberative Process |
| HHC904-00590073 | 10/3/1990 | Memo and attachments | FDA Comments on OIG's Report, " The DHHS Enforcement of Regulations Prohibiting Medicaid Payments for Less-Than-Effective Drugs" July 1990 | Holston, Sharon Smith | Associate Commissioner for Management and Operations, FDA | Director, Office of Management, OASH | | | DP Deliberative Process |
| HHC904-00740075 | 10/31/1994 | Note | responding to request for legal opinion Re: Formulary Restrictions Based on Age Criteria. | Salhus, Mary | OGC/HCFD | Gaston, Sue | | | DP Deliberative Process, AC Attorney-Client |
| HHC904-00760080 | 07/7/1994 | Memo and attachments | Discussing Legality of Colorado implementing online claims system and charging Transaction Fee to Pharmacist with attachments | Gaston, Sue | | | | | AC Attorney-Client, DP Deliberative Process |
| HHC904-00810082 | 08/21/1990 | Memo | discussion of OGC Opinion Regarding Waiver request concerning Provider Agreement and Direct Payment Issues | Hickman, William L. | Director , Office of Medicaid Policy | | | | DP Deliberative Process |
| HHC904-0083-0089 | 01/23/1990 | Memo | Legal opinion of Proposed Tennessee arrangement for home and community based service payments | Fisher, Barbara, Attorney | HHS/Office of the Secretary/OGC | Buto, Kathleen A. | Director, BPD | | DP Deliberative Process, AC Attorney-Client |
| HHC904-00900116 (Released 091-115) | 09/7/1989 | Request for information and attachments | Response from State of Tennessee to HCFA Request for Additional Information re: HCBS Adult MR Waiver in the State of Tennessee | | | | | | DP Deliberative Process |
| HHC904-01170120 | 11/6/1991 | Memo and attachments | Request for legal opinion re: Cost Savings of Requiring Nursing Homes to Purchase their pharmaceutical supplies from a single state selected wholesaler- Action | Hickman, W. L. | Director, Office of Medicaid, Policy | Jaye, Bob | Office of the General Counsel, HHS | | DP Deliberative Process AC Attorney Client |
| HHC904-01450154 | XX/XX/XXXX | Letters and attachments | Draft response to letter re: Oregon's state plan amendment to redefine the state's EAC for drugs from AWP minus 14 percent to AWP minus 15 percent. | Smith, Dennis G. | Director | Coster, JohnM., Ph.D., R., PH. | Vice President, Policy and Programs, National Association of Chain Drug Stores | Garza, Maria, Seattle Regional Office | DP Deliberative Process |

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|-----------------|------------|------------------------------------|---|-----------------------------|--|---|--|-------------------------------|-------------------------|
| HHC904-01790181 | XX/XX/XXXX | Draft letter | Draft response to letter re: 2/11/03 update to federal Upper Limit List for generic drugs | Reed, L | Co-Director, Pharmacy Team, CMS | Costar, J. M., PH.D., R. Ph. | Vice President, Policy and Programs | | DP Deliberative Process |
| HHC904-01820191 | 11/7/2002 | Draft report and handwritten notes | Discussing Options for Obtaining Better Drug Pricing Data for Both Medicaid and Medicare to obtain AWP figures | | | | | | DP Deliberative Process |
| HHC904-06000601 | XX/XX/XXXX | Draft Report and attachments | Discussing proposed recalculation of Medicaid rebate formula, specifically addressing Medicaid pharmacy reimbursement. Also contains discussion of FUL. | | | | | | DP Deliberative Process |
| HHC904-06020602 | 03/13/2003 | Email | Requesting approval & effective date of Oklahoma SPA authorizing state's prior authorization program | | | Pelter, Cindy | | Blunt, Ford; Glaspie, Shirley | DP Deliberative Process |
| HHC904-06030606 | XX/XX/XXXX | Draft memo | Subject; Determination of Medicaid Prescription Drug Estimated Acquisition Cost (EAC); Discussing generally, state plan amendment requests that propose to change reimbursement methodology and how to analyze these state plans. | | Director, Family and Children's Health Program Group | | Director, Center for Medicaid and State Operations | | DP Deliberative Process |
| HHC905-10831599 | XX/XX/XXXX | Report | Appendix II Top 60 Drug Data, Final Report on the "Prices Established by the Private and Public Sectors for Drugs Also Covered Under Medicare Part B" | Jing Xing Technologies, Inc | | | | | DP Deliberative Process |
| HHC906-00010002 | 1/23/2002 | Memo - | Decision Memo - Discussion of Carrier investigations of payment for Lupron (HCPCS Code J9217) | | | | | | DP Deliberative Process |
| HHC906-00150018 | 6/12/2002 | Letter w/attachment | letter w/e-mail chain re: Discussion of overpayment collection regarding Lupron. | Weinerman, Ernest | | Foster, Robert | | | DP Deliberative Process |
| HHC906-00190022 | 5/10/2002 | Letter w/attachment | letter w/e-mail chain re: Discussion of overpayment collection regarding Lupron. | Weinerman, E. | | Schilling, P. G. Blue Cross Blue Shield, Arkansas | Branch Chief | | DP Deliberative Process |
| HHC906-00230029 | 4/22/2002 | Letter w/attachment | Letter w/e-mail chain requesting information regarding study of payment for lupron | Weinerman, E. | | Patricia G. Schilling | | | DP Deliberative Process |

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| HHC906-00300038 (Released 0034) | 5/22/2002 | e-mail w/attachments | Letter w/e-mail chain requesting information regarding study of payment for lupron | Weinerman, E. | | Yablon, M. X. | | | DP Deliberative Process |
| HHC906-00390045 | 5/23/2002 | Letter w/attachment | requesting guidance on reviewing the top 20 physician billers of Lupron in Missouri | Weinerman, E. | | Karpoff, G. W. | Blue Cross Blue Shield, Arkansas | | DP Deliberative Process |
| HHC906-00460050 | 4/25/2002 | Email and attachment | Letter w/e-mail chain requesting information regarding study of payment for lupron | Weinerman, E. | | Ziegler, Sonia | | | DP Deliberative Process |
| HHC906-00510054 | 3/25/2002 | Email | letter w/e-mail chain re: Discussion of overpayment collection regarding Lupron. | Weinerman, E. | | Hatcher, Sheila | | | DP Deliberative Process |
| HHC906-00900098 (Released 0090-91) | 06/17/1991 | Memo and attachment | Medicare Drug Pricing (Your memo dated July 3, 1990); Discussing NPrM not to include drugs in the Physician Fee Schedule and pay for drugs at AWP minus 15% discount. | Buto, K. A. | Director, Bureau of Policy Development | | Associate Regional Administrator, Division of Medicare, Dallas | | DP Deliberative Process |
| HHC906-00990165 | 11/17/1998 | Fax and attachment | Attaching draft of Change Request # 745-Implementation of 1999 Payment Limit for Medicare Drugs. Also contains handwritten notes and other draft memoranda leading up to publication of this change request. | Shaver, Carrie | | Vogel, Mark | | | DP Deliberative Process |
| HHC906-01660171 (Redacted portions on 170) | 06/13/1991 | Memo and attachment | Request for Guidance on Limiting the Charge for Drugs/ Biologicals provided by Physicians (Your memo dated 11/8/90) [copy of HHC903-08650868 | Buto, K. A. | Director, Bureau of Policy Development | Chief, Carrier Operations Branch | Associate Regional Administrator, Region V, Chicago | | DP Deliberative Process |
| HHC906-01870192 | 11/6/1996 | Typewritten notes | Notes of conference call re: AWP pricing and RVU's (Relative Value Units) | | | | | | DP Deliberative Process |
| HHC906-02230227 | XX/XX/XXXX | Memo | Draft of comments to Michigan State Plan Amendment 01-015 (draft) regarding reimbursement and supplemental rebate calculation. | Reed, Larry | Director, Division of Medicaid and State Operations, CMS, HHS | | Associate Regional Administrator, Division of Medicaid, Region V, Chicago | | DP Deliberative Process |
| HHC906-02400240 | XX/XX/XXXX | Notes | Handwritten notes re: Supreme Court request for HHS to express views on Maine issues. | | | | | | DP Deliberative Process |

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| HHC906-02490950 | 12/18/1995 | Memo with handwritten notes | Draft of Wisconsin State Plan Amendment (SPA 95-026, 95-027, 05-028) Request for Additional Information. This SPA proposes new reimbursement methodology for medication management services. | Wardwell, Robert | Director, Office of Medical Services, Medicaid Bureau | | Associate Regional Administrator, Division of Medicaid | Regional Administrator, Division of Medicaid, Region V. | DP Deliberative Process |
| HHC906-02510254 | 10/2/1995 | Letter | Draft of Wisconsin State Plan Amendment (SPA 95-026, 95-027, 05-028) Request for Additional Information. This SPA proposes new reimbursement methodology for medication management services. | Rinaldo, Lucille M. | Health Insurance Specialist, Division of Medicaid and Managed Care Programs | Piper, Kevin | Director, Bureau of Health Care Financing, Wisconsin Department of Health and Social | | DP Deliberative Process |
| HHC906-02920296 | 12/10/1997 | Email | Attaching draft of language to be used in response to inquiries regarding the issue of least costly alternative and payment for Lupron and Zolodex. | Neimann, R. | | Rominger, P.; Carpenter, C. | | | DP Deliberative Process |
| HHC906-02970303 | 12/10/1997 | Email | Attaching draft of language to be used in response to inquiries regarding the issue of least costly alternative and payment for Lupron and Zolodex. | Heygster, Anita | | Rominger, Pamela | | Garrison, D.; Nancy S. | DP Deliberative Process |
| HHC906-0304-0306 | 08/15/1997 | Draft language | Language to be used in response to inquiries re: payment of Lupron | Niemann, R. | | | | Jacobs, Tom | DP Deliberative Process |
| HHC906-03140316 | 01/27/1997 | Email and attachment | Discussion of instructions to Carrier Medical Directors regarding least costly alternative policy. | Sigmund, James | | Contreas, A. | | | DP Deliberative Process |
| HHC906-03170317 | 04/12/1995 | Draft language | Draft language to be used in responding to Dr. Timothy C. Hlavinka regarding Medicare coverage of Zolodex. | | | Colbert, Dorothy | | | DP Deliberative Process |
| HHC906-03180325 (Released 318-19) | 06/17/1991 | Memo and attachment | Medicare Drug Pricing (Your memo dated July 3, 1990) Discussing NPRM not to include drugs in the Physician Fee Schedule and pay for drugs at AWP minus 15% discount. | Buto, K. A. | Director, BPD | Christenberry, M. J. | Associate Regional Administrator, Division of Medicare, Dallas | | DP Deliberative Process |
| HHC906-03260332 | 07/10/1990 | Memo | Regional Office Recommendations for Program Changes to Address Agency Initiatives. Recommends changes to carrier and intermediary drug reimbursement policies. | Christenberry, M. J. | | Gagle, Barbara | Director, BPO | | DP Deliberative Process |
| HHC906-03340336 (Released 336) | 09/16/1998 | Letter and attachment | Draft Response to 4/13/1998 letter re: reimbursement rate for Gamma Globulin injection. Also contains discussion of Lupron litigation. | Duncan, Shirley | Chief, Health Plan Providers Branch, HCFA Dallas | Burns, W.E. M.D. | | | DP Deliberative Process |
| HHC906-03370338 | 11/3/1997 | Route slip and attachment | State plan amendment consideration. Handwritten notes analyzing Texas's proposed reimbursement methodology. | Reiden, J. | | | | | DP Deliberative |
| HHC906-03390339 | XX/XX/XXXX | Form | Batch Information Re: Lupron MDL Subpoena | | | | | | DP Deliberative |
| HHC906-05050505 | 10/8/1999 | Email | Discussion of Least Costly Alternative Policy and Lupron, Zolodex, and ESRD services. | Pilley, Mark | Mutual of Omaha | Nichols, K. | | Cox, Kathy | DP Deliberative |

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| HHC906-05140536 (Released 514-515, 519-520, 529-536) | 12/20/1999 | Fax and attachment | Draft of policy memorandum to correct code J2405 (Monitored Anesthesia policy, special circumstances when the Anesthesia care needs to be monitored. Also contains e-mail discussion of reimbursement methodology for Part B injectable drugs. | Moore, Pat | | Murff, Donna | HCFA | | DP Deliberative Process |
| HHC906-05580559 | XX/XX/XXXX | Letter (draft) | Draft letter discussing Colorado's State Plan Amendment (SPA) 02-011, which would modify the estimated acquisition cost for prescription drugs, increasing the discount to AWP less 14% for brand name drugs and AWP less 45% for generics. | Reed, L. | Co-Director, Pharmacy Team, CMS | Chaumont, Vivianne | Director, Office of Medical Assistance, Dept. of Health Care Policy & Financing | Ericson, Spencer, Acting Associate Regional Administrator, | DP Deliberative Process |
| HHC906-05600561 | XX/XX/XXXX | Medicare Payment Policy and Email | Internal discussion and proposed policy clarification regarding Medicare Payment Policy for Implantable infusion Pump and the Drugs Used to Refill the Pump | Merrill, Jill | | | | | DP Deliberative Process |
| HHC906-05770578 | XX/XX/XXXX | Change request 2869 | Draft Program Memorandum Intermediaries/Carriers - Subj.: Drug Pricer Quarterly Update | | | | | | DP Deliberative Process |
| HHC906-05850586 | XX/XX/XXXX | Draft | Draft letter discussing Colorado's State Plan Amendment (SPA) 02-011, which would modify the estimated acquisition cost for prescription drugs, increasing the discount to AWP less 14% for brand name drugs and AWP less 45% for generics. | Reed, Larry, Department of Health & Human Services | Co-Director, Pharmacy Team, | Allen, Richard, Office of Medical Assistance | Director | Ericson, Spencer, Denver Regional Office | DP Deliberative Process |
| HHC906-05870590 | XX/XX/XXXX | Draft Report | Draft of Q&A response to the State of Montana SPA 03-003, focusing on covered outpatient drugs and Medicaid drug rebate. | | | | | | DP Deliberative Process |
| HHC906-05910592 | XX/XX/XXXX | Draft letter | Draft request for information from Montana regarding State Plan amendment (SPA) 03-002. The amendment proposes to change the reimbursement methodology for the Estimated Acquisition Cost representing Average Wholesale price. | Reed, L. | Co-Director, Pharmacy Team | Gray, Gail | Director, Health Policy & Services Division, Dept. of Public Health and Human Services | Anderson, Todd; Dunstan, Diane | DP Deliberative Process |
| HHC906-05930594 | XX/XX/XXXX | Draft letter | Draft letter discussing Colorado's State Plan Amendment (SPA) 02-011, which would modify the estimated acquisition cost for prescription drugs, increasing the discount to AWP less 14% for brand name drugs and AWP less 45% for generics. | Reed, L. | Co-Director, Pharmacy Team | Rinerston, Karen | Director, Office of Medical Assistance, Dept. of Health Care Policy & Financing | Ericson, Spencer | DP Deliberative Process |
| HHC907-00010002 | 12/16/1998 | Typed Note | Re: Lupron v. Zoladex LMRP Issue; policy clarification; strategy recommendations regarding proposed LMRP | GNR | | | | | DP Deliberative Process |

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| HHC907-00030003 | 12/16/1998 | Typed Note | RE: lupron v. Zoladex LMPR Issue; policy clarification; strategy recommendations regarding proposed LMRP | GNR | | | | | DP Deliberative Process |
| HHC907-00040006 | XX/XX/XXXX | Handwritten Notes | Re: Lupron / Zoladex; Notes on discussion regarding payment for these drugs. | | | | | | DP Deliberative Process |
| HHC907-00070008 | 11/20/1998 | Draft letter | Re: Proposed Local Medical Review Policy regarding coverage for Lupron; explanation of LMRP process and clarification of issues raised in initial letter | Bruk, Mary E. | Medicare Contractor Management Branch, Division of Beneficiary Services | | | | DP Deliberative Process |
| HHC907-00090009 | 10/29/1989 | Handwritten note | Re: CA Proposal for Drug Reimbursement Methodology; implementation of reimbursement procedures | | | Masleowitz, Jerry | | | DP Deliberative Process |
| HHC907-00100016 | 12/28/1989 | Memo with attached draft | An Operational Definition of "Aggregate Test" for purposes of the EAC at 42 CFR 447.331; request for confirmation that draft accurately reflects HCFA policy | McDonough, Lawrence L. | Associate Regional Administrator, Division of Medicaid, Region IX | Buto, K. | Director, BPO | Schutzan, Fred, Director, Bureau of Quality Control | DP Deliberative Process |
| HHC907-00740088 (Released 74-75) | 7/22/1998 | Draft | Distribution of information for the 1998 Influenza and Pneumococcal Campaign--ACTION; revised questions and answers concerning coverage and payment policies | Jones, O. Sharon | Chief, Customer Relations Branch, Division for Beneficiaries, Health Plans and Providers | Retention date: December 31, 1999 | | | DP Deliberative Process |
| HHC907-01170124 | 10/28/1996 | Draft memo and attachment | Inappropriate Physician Fee Schedule Payments in Hospitals; explanation of basic payment principles and whether certain payments would qualify as incident to services | Cusick, Elizabeth, Director & Stewart, Streimer, Director | Office of Physician & Ambulatory Care Policy, BPD & Office of Program Requirements, BPO | All Associate Regional Administrators | Division of Medicare | | DP Deliberative Process |
| HHC907-01250128 | 12/7/1998 | Email and attachments | Lupron & Zoladex; discussion of least costly alternatives | Baier, Fay | | Schoen, T. | | | DP Deliberative Process |
| HHC907-01290129 | 05/3/1996 | Short Email | Payment policy For Zoladex and other drugs in similar circumstances. | Grabowski, John | | WPPROFS HCFASFO CM02 | | Schoen, T. | DP Deliberative Process |
| HHC907-01500151 | 02/1/1999 | Email | Dr. Mollen and Flu/PPV Reimbursement; explanation of the logic of both the pricing of the Flu/PPV and of the administration of the vaccine | Schoen, Teresa | | San Francisco.SF0 1.Calma, Denver.Den1. Rstrub | | Wong, H, White2, M; Shoemaker M | DP Deliberative Process |
| HHC907-03260326 | XX/XX/XXXX | Handwritten notes | Reimbursement of Epogen; statutory limits and comparison to other drugs. | Schoen, T. | | | | | DP Deliberative Process |

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| HHC907-04290440 (Released 432-40) | 06/22/1998 | Email and attachments | Single Drug Pricing File; AWP simplified process; explanation of background of teleconference regarding how carriers calculate payment allowances | Ring, Linda | | Ross, F.; Sprenz A. | | DP Deliberative Process |
| HHC907-04880494 | XX/XX/XXXX | Draft Report | CIGNA Contractor Performance Review Report; background, review methodology of CIGNA-DMERC's performance and how payment amounts are calculated for Durable Medical Equipment, Prosthetics, Orthotics and Supplies. | | Schoen, T. | | | DP Deliberative Process |
| HHC907-05520557 (Released 553-557) | 05/3/1996 | Email | Discussion of Payment For Zoladex and other drugs under similar circumstances. | Grabowski, John | | Schoen, T. | | DP Deliberative Process |
| HHC907-05580558 | 10/24/1996 | Short Email | Regarding extent of discretion a carrier medical director has in paying for equivalent drugs with different prices | Schumaker, Bernadette | | Ault, T. | | Neimann, R.; Bagley, G.; Primack, A. DP Deliberative Process |
| HHC907-05600562 | XX/XX/XXXX | Comments | CR#1232/N464 Accurate Average Wholesale Price Data for Drugs; edits of submitted memorandum | Gattuso, John | | | | Stokayer, A.; Slisker; Blumenfeld, A; Scolonferrer DP Deliberative Process |
| HHC907-06500693 | 03/10/1997 | Email and attachments | Discussion of Sandimmune pricing; and discussion of alterations to NDC and HCPCS Codes | Schoen, T. | | Riley, Carolyn | | DP Deliberative Process |
| HHC907-07230724 | 11/20/1997 | Notes | Handwritten notes from phone conversation with Barbara Douglas; discussion of payment practices for specific Jcodes. | Schoen, T. | | | | DP Deliberative Process |
| HHC907-07250729 | 10/29/1998 | Notes and attachment | Handwritten notes; Cigna - 1988 CPE Review; pricing array; calculation of AWP for albuterol | Schoen, T. | | | | DP Deliberative Process |
| HHC907-07300739 | XX/05/1998 | Email and attachment | Draft of CPE Review of CIGNA-DEMERC regarding Inherent Reasonableness (IR); and draft contractor review report regarding payment amounts for DMEPOS. | Schoen T. | | Underhill J. | | Bell, B.; Kendall, C. DP Deliberative Process |
| HHC907-07670770 | 07/24/1996 | Note | Handwritten note on conversation with Mary Lipinsky re: Immunex; new drug pricing info and AWP calculation. | Schoen, T. | | | | DP Deliberative Process |

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| HHC907-08000816 | 07/27/1998 | Email and attached IR Project | National DMERC IR Project (Albuterol Nebulizer (Aerosol Inhaled) Drugs; explanation of project; revision of draft of DMERC IR notice | Kaiser, Joel | | Finn, C.; Eiler, C.; Stone, R.; Douglas, B.; Leads | | Long2, W.; Rutemueller, W.; Wardell, B.; Spalding, J. | DP Deliberative Process |
| HHC907-08170826 | 04/1/1998 | Notes | Handwritten notes on IR Teleconference; outline of process for IR; question/answer regarding hypotheticals as applied to DMERC | Long, Bill; Schoen, T. | | | | | DP Deliberative Process |
| HHC907-08270836 (Released 830-32, 834-36) | 04/1/1998 | Broadcast fax with attachments | Listing of IR Candidates, Report of contacts and correspondence for 10am IR Conference call; letters from parties to HCFA regarding fee payment for devices. | Kaiser, Joel, BPO OCCIP | Chronic Care Purchasing Policy Group | Greer, Scott; Thomas Irvin; Schmidt, Nancy; Kozak, Debbie; Finn, Colleen; Eller, Cheryl; Stone, Robin; Douglas, Barbara; Edge, Mike | Lead DME RO's, DMERCS, and SADMERC | | DP Deliberative Process |
| HHC907-08370851 | 04/5/1999 | Email w/attachments & handwritten notes | Draft DMERC IR Comments & Response for review; request that Medical Directors also review document; regarding statistical validity of pricing data, general process issues, requirements of the Administrative Procedures Act and other legal issues | Kaiser, Joel | DME | Finn, C.; Eiler, C.; Stone2, R.; Douglas, B.; Leads | Huges, P.; Oleck, A.; Rutemueller, W.; Long2, W.; Wardwell, B.; Dr. Hoover | | DP Deliberative Process |
| HHC907-08520860 | 04/14/1998 | Notes handwritten | RE: Inherent Reasonableness teleconference; Bulletins-cost factors; draft of strategy for implementing IR standard. | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-08610862 (Portions redacted) | 04/29/1998 | Email | Re: Inherent Reasonableness -contact with retail stores with resulting retail pricing on albuterol sulfate | Zone, Bob | | Schoen, T.; Ballantine, L.; HCFA, Kaiser, J. | Underhill, J.; HCFA, Medical Direct | | DP Deliberative Process |
| HHC907-08630874 | 04/30/1998 | Handwritten notes | RE: Inherent Reasonableness; Bulletin Funds; discussion of retail prices and state pricing | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-08750881 | 05/14/1998 | Handwritten notes | RE: Inherent Reasonableness teleconference; brainstorming regarding retail prices | Schoen, T. | | | | | DP Deliberative Process |

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| HHC907-09050911 | 06/4/1998 | handwritten notes | IR Teleconference - IR Project Albuterol (K0505) = Nebulizer Drug; progress of analysis and usage of Region D's spreadsheet format | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-09450951 | 06/17/1998 | Email w/ handwritten notations and attached handwritten notes | re: IR Call; minutes of call detailing discussion of each member's contribution; plans for following Bulletin | Costello, A.; Schoen, T. | | IR Group | | McWright, L.; Washington, DC | DP Deliberative Process |
| HHC907-09530956 | 06/24/1998 | Email message w/handwritten notes dated 6/24/98 & Email message 6/25/98 | RE: IR Survey w/ handwritten notes regarding proper pricing; DMERC's receipt of accurate info | Rutemueller, W.; Schmidt, N.; Long, W.; Cohen, J. | | Vogel, M.; Thomas, T. | | Long2, W.; Kaiser, J.; Spalding, J.; Costello, A.; Cohen, J. | DP Deliberative Process |
| HHC907-09570963 | 07/9/1998 | Handwritten notes | RE: Inherent Reasonableness; progress on receipt and analysis of state surveys | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-09680974 | 07/20/1998 | Handwritten notes | Re: IR Call; progress notes on pricing formulas for albuterol and other products | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-09750977 | 07/21/1998 | Draft Notes of Meeting | Inherent Reasonableness Briefing (IR) -7/21/98; DMERC's implementation of the BBA; methodology of study and agreement of participants | | | | | | DP Deliberative Process |
| HHC907-09780978 | XX/XX/XXXX | Draft | Draft Initial Notice of Inherent Reasonableness regarding certain HCPCS codes. Discusses application of IR to Medicare Part B payments. | | Cigna Medicare, DMERC Pricing Unit | | | | DP Deliberative Process |
| HHC907-09900992 | 07/29/1998 | Handwritten notes | RE : IR Call; progress notes on pricing methodologies | Schoen, T. | | | | | DP Deliberative Process |
| HHC907-09970999 (Released 997-98) | 07/29/1998 | Email messages w/attachment | Suggested edits for draft Notice of Inherent Reasonableness | Kaiser, J.; Costello, A. | Finn, C.; Eller, C.; Stone, R.; Douglas, B.; Douglas2, B.; IR Group | | Vogel, M.; Thomas, I, | | DP Deliberative Process |
| HHC907-10081008 | 11/3/1998 | Handwritten notes | Re: CIGNA DMERC-CPE< IR Sample 6/17/98 Spreadsheets; list of spreadsheets with comments and survey calculations. | Schoen, T | | | | | DP Deliberative Process |

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| HHC907-10091012 | 11/16/1998 | Email w/attachments re : Region D Comments to the IR | Region D's questions & answers to comments received for IR project; summary of comments and responses | Douglas, B., CIGNA | | Kaiser, J., HCFA | | Schoen, T., Underhill, J. | DP Deliberative Process |
| HHC907-10691073 (Released 1072-73) | XX/XX/XXXX | Memo | WA 02-022 With Attachment | Myers, Ann | | Howell, K | | | DP Deliberative Process |

CARRIER PRIVILEGE LOG

CARRIER PRIVILEGED DOCUMENTS LOG

| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|-----------------|------------|------------------------------------|--|---|-----------------|---|--------------------|--|---|
| AWP901-0005008 | 12/12/1996 | E-mail | E-Mail messages Re: Vogel Letter-Zeneca w/ attached Medicare B News, Issue No. 148 w/handwritten notations. E-Mails relate to predecisional deliberations concerning reimbursement for Lupron and Zolodex. | Imgrund, Joseph; Muscalus, Robert | | Pat McKee, Pat; Manning, Vicky; Krushinsky, Mark; Wienski, Terri | | Moynihan, Eileen; O'Connell, Brent | DP Deliberative Process |
| AWP901-00150016 | 1/22/1997 | E-mail messages | Re: Zoldex vs Lupron w/ handwritten notation. E-mails relate to draft article concerning Zolodex and Lupron reimbursement. | Imgrund, Joseph; Bucek, Patricia | | McKee, Pat; Smith, Cynthia; Imgrund, Joseph; Lenker, Ed | | Schoener, Lynette; Bucek, Patricia | DP Deliberative Process |
| AWP901-00170018 | 1/23/1997 | Various e-mail messages | Re: Zoldex vs Lupron in reply to 1/22/1997 letter. E-mails relate to draft article concerning Zolodex and Lupron reimbursement. | McKee, Pat | | Osman, Anita | | | DP Deliberative Process |
| AWP901-00210022 | 1/23/1997 | E-mail messages | Re: Vogel Letter - Zeneca - in reply to letter of 11/14/1996. E-Mails relate to predecisional deliberations concerning reimbursement for Lupron and Zolodex. | McKee, Pat | | Osman, Anita | | | DP Deliberative Process |
| AWP901-00250027 | 9/12/2000 | Letter | Draft of Letter to Member of Congress re: HCFA carriers' drug payment policy. | DeParle, Nancy-Ann Min | Administrator | Member of Congress | | | DP Deliberative Process |
| AWP901-01610169 | 4/23/1999 | Fee Schedule | Fee Schedule for Unlisted Drugs 1999 w/ handwritten notations | | | | | | DP Deliberative Process |
| AWP901-01720172 | 8/20/2002 | E-mail messages | Subj: Re: Summary of aranesp issue - attorney/client confidential w/handwritten notation | Stone, John M. | | Neville, John B. | Legal.BCBSU/TBG | | AC Attorney-Client, DP Deliberative Process |
| AWP901-01730173 | 8/20/2002 | Phone message | Message for John Neville from Anne Vickery on 8/20 w/ handwritten notes dated 8/21/02 | S. E. | | Neville, John B. | | | DP Deliberative Process, AC Attorney-Client |
| AWP901-01910192 | 3/6/2003 | E-mail messages | Subject Darbepoetin - Aranesp - pricing | Stone, John M. | | Neville, John B.; Tohill, Lora A., GOVMNT/BCBSU/TBG; Kreck, Boyd, GOVMNT/BCBSU/TBG | Legal.BCBSU/TBG | Cannaday, Jennifer, LEGAL/BCBSU/TBG , Mitchell, John, GOVMNT/BCBSU/TBG | DP Deliberative Process, WP Work Product |
| AWP901-02020204 | XX/XX/XXXX | Spreadsheet | Darbepoetin Alfa (Aranesp) - Epoetin Alfa Comparison | | | | | | DP Deliberative Process |
| AWP901-02050208 | 4/15/2002 | E-mail | Re: Aranesp | Hackathorn, Kathy; Payne, Carolyn, Wichita Nephrology Group | | Moore, Darrell | | Watson, Les, Price, P. | AC Attorney-Client |
| AWP901-02090212 | 10/12/2002 | E-mail message w/attached analysis | Coverage determination for pegfilgrastim (Neulasta) | Price, Patrick | | Stone, J. M. | | | WP Work Product |
| AWP901-02130222 | 5/18/1999 | Minutes | Steering Committee Conference Call Minutes. Minutes record predecisional recommendations, discussions, and the individual opinions of contractor medical directors and HCFA staff on a variety of topics. | | | Sheridan, D. Dr.; Adamson, J., Dr.; Cox, E. Dr.; Satya-Murti, S. Dr.; Ramirez, J., Dr.; Staples, P.; Dr.; Perez, D.; Dr.; Oleck, A., Dr.; Lurvey, A., Dr.; Krubsack, A., Dr.; Waldmann, G., Dr.; Alexander, J., Dr.; Marciniak, T., Dr.; Primack, A., Dr.; Feinberg, L., Dr.; Skinner, D.; Scally, K.; Geyer, L.; Olshan, S.; Combs, M. & Hippler, S. | | | DP Deliberative Process |
| AWP901-02230225 | 6/23/1997 | Handwritten note w/attachments | Re: last steering committee consensus concerning procrit. Contains discussion of predecisional recommendations concerning coverage of procrit. | Dr. Price | | Priscilla | | | DP Deliberative Process |
| AWP901-02260228 | XX/XX/XXXX | SPREADSHEET | Darbepoetin Alfa (Aranesp) - Epoetin Alfa Comarison | | | | | | WP Work Product |

CARRIER PRIVILEGED DOCUMENTS LOG

| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|-----------------|------------|--|---|-------------------------------|---------------------------|--|--|---|-------------------------|
| AWP901-02290242 | 1/3/2002 | Rough Draft | Letter re: Desialylated erythropoietin. Contains suggested changes to draft letter concerning Aranesp coverage and reimbursement. | Price, Patrick, M. D., FACS | Medicare Medical Director | Huetsch, Randy L. | Payer/Provider Relations Manager, Amgen, Inc | Stanard, Jacqui; Rhoads, Donna; Dennison, Jane; Sean; Biotech, Ortho | DP Deliberative Process |
| AWP901-02430255 | 7/19/2002 | Handwritten draft | Draft concerning Aranesp reimbursement. | | | | | | DP Deliberative Process |
| AWP901-02560304 | XX/XX/XXXX | Fax transmission documents and | Rough drafts of document concerning Aranesp reimbursement. | | | | | | DP Deliberative Process |
| AWP901-03050305 | 4/9/2002 | E-mail message w/fax transaction report dated 4/15/02 | EMail messages reflecting predecisional recommendations on Aranesp reimbursement. | Price, Patrick | | Price, L.; Niemann, R.; Schneider, Mary | | | DP Deliberative Process |
| AWP901-03060308 | 4/8/2002 | E-mail messages & Fax transaction report dated 4/15/02 | E-mail containing recommendations for policy concerning Aranesp reimbursement. | Murff, Donna; Niemann, Robert | CMS/HHS | Ernest, Cathy; Timperley, Jenny | BCBSNE | Price, P; Stamp, Gigi; Mason, Angela; McGuirk, Glenn; Richter, Henry; Price, Lana; Radke, Susan | DP Deliberative Process |
| AWP901-03090334 | 6/11/2002 | Correspondence file | Correspondence to and from Melanie Combs concerning carrier survey on Aranesp reimbursement. | | | | | | DP Deliberative Process |
| AWP901-03350341 | 6/11/1002 | Survey w/attachments Email messages re: Important Survey re: Aranesp | Melanie Combs Data Survey | Price, P., Combs, Melanie | | | | Zerbe, Annette; Gross, Bill; Berkey, Julie; Combs, M.; Murti, Satya S.; Lichter, V. | DP Deliberative Process |
| AWP901-03420344 | 4/2/2002 | Email | E-mail reflecting predecisional recommendations/opinions on Aranesp treatment. | Feinberg, Laurie | CMS HHS | Price, P.; Stanard, J.; Feinberg, J.; Bryan, M.; Foster-Reilly, N.; DeiCas, R. | | Zerbe, A.; Rhoads, D.; Schneider, M.; Douglas, P. | DP Deliberative Process |
| AWP901-03450354 | 4/1/2002 | Correspondence file | Kay, Terry CMS - letters re Aranesp coverage, with recommendations and suggestions. | Patrick, P. | Medicare Medical Director | Kay, Terrence L. | | Combs, M.; Kang, Jeffrey, M.D.; Stone, J., M.D.; Stanard, J.; Bryan, M. | DP Deliberative Process |
| AWP901-03640368 | 4/9/2002 | Email to and from Lana Price, CMS | E-mails reflecting predecisional deliberations on Aranesp coverage and reimbursement. | Price, Patrick. | | Murti, M.; Price, L.; Niemann, R.; Schneider, M. | | | DP Deliberative Process |
| AWP901-03700375 | 14/10/2002 | Correspondence file | Email and correspondence re: Aranesp to and from Stanard, Jacqui R. O. EMail messages reflect predecisional recommendations on Aranesp reimbursement | Price, P. | | Stone, J. | | Schneider, M. | DP Deliberative Process |
| AWP901-03760398 | 10/21/2003 | Email | Confidential: Re-Review fo E CR 2963-- Change in Coding on Medicare Claims for Aranesp and EPO 2003. E-mails commenting on draft Change in Coding on Medicare Claims for Arenasp and EPO. | Price, P. | | Richter, H. | | Nixon, I.; Zerbe, A.; Rhoads, D.; Burke, P.; Brown, Linda; Shelton, Ann; Caldwell, Sharil; Moore, P.; Sheridan, David; Stone, J.; Gross, B. | DP Deliberative Process |
| AWP901-03990414 | 10/21/2003 | Email | Subject: CONFIDENTIAL: Re-Review of E CR 2963-Change in Coding on Medicare Claims for Aranesp & EPO. E-mails commenting on draft Change in Coding on Medicare Claims for Arenasp. | Stone, J. | | Price, P. | | Richter, H.; Nixon, I.; Zerbe, A.; Rhoads, D. | DP Deliberative Process |
| AWP901-04150424 | 2/15/2001 | Draft | Edits to draft of document concerning chronic renal failure reimbursement issues (Handwritten). | | | | | | DP Deliberative Process |
| AWP901-04250466 | 10/9/2002 | Draft Policy | Medicare Part B - KS/NE/W.MO-Synthetic Erythropoietin and Non Renal Failure. Draft policy with handwritten notations suggesting changes. | | | | | | DP Deliberative Process |

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| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|------------------|------------|-----------------------------|---|---|-----------------------------------|---|--------------------|--|-------------------------|
| AWP901-04670542 | 9/25/2002 | Bibliography (handwritten) | Jama Bibliography Sept. 25, 2002, Vol 228 #12 pgs 1499-1507. Draft with comments suggesting changes. | | | | | | DP Deliberative Process |
| AWP901-05430563 | 10/21/2003 | Email | Correspondence file for Richte, Henry, CMS - Subj: CONFIDENTIAL: Re-Review of E CR 2963-Change in Coding on Medicare Claims for Aranesp & EPO. E-mails commenting on draft Change in Coding on Medicare Claims for Arenasp and EPO. | Price, P. | | Richter, H. | | Nixon, I.; Zerbe, A.; Rhoads, D.; Burke, P., Brown, Linda; Shelton, Ann; Caldwell, Sharil; Moore, P.; Streets, Brad; | DP Deliberative Process |
| AWP901-05640566 | 6/2/1999 | Correspondence | Data Lauren Geyer - Correspondence to and from Lauren Geyer re: Procrit. E-mail contains suggestions concerning EPO and Procrit coverage and reimbursement policies. | Price, P. | | Geyer, L., HCFA | | Murti, Satya, S. | DP Deliberative Process |
| AWP901-05670568 | 6/4/1999 | Email | Procrit - Reply to E-Mail containing suggestions concerning EPO and Procrit reimbursement. | Price, Patrick | | Geyer, L., | | | DP Deliberative Process |
| | | | | | | | | | |
| AWP901-05700570 | XX/XX/1996 | Data Analysis | Data Analysis of Number of Claims (July - December 1996 Procrit) | | | | | | DP Deliberative Process |
| AWP901-05710571 | 10/10/1997 | Handwritten Notes | Handwritten Notes Re: Procrit coverage policy and whether it should change. | | | | | | DP Deliberative Process |
| AWP901-05720572 | 5/15/1998 | Email | Procrit/EPO | Price, Patrick | | Mylinda, Wilhite; Evans, Diana; Schnneider, Mary; Satya-Murti S; Gable, Joan; Burke, Priscilla; Hainline, Barbara | | | DP Deliberative Process |
| AWP901-0573-0590 | 3/15/2001 | Email w/attachment | Steering Committee Agenda - March 2001 w/attached email & handwritten note re: Discussion Guide for LHRH. Agenda includes predecisional suggestions/recommendations for policy changes. | Murti, Satya S. | | Haller, Marcia | | Price, P | DP Deliberative Process |
| AWP901-05930593 | 5/17/1991 | Memorandum | Carrier coverage of the Drug Filgrastim (Neupogen, a chemotherapy drug) and whether national policy was required. | Warren, Richard | | Director, Office of Coverage Policy, BPD | | | DP Deliberative Process |
| AWP902-03130319 | 5/1/2001 | Draft | Request for Information in Narrative Report MS Word Format. Draft with handwritten suggestions/recommendations. | King, Colleen, Healthnow; Eiler, Cheryl, Anthem; Douglass, Barbara, Cigna; Stone, Robin, Palmetto; | Government Benefits Administrator | | | | DP Deliberative Process |
| AWP902-03200325 | 5/1/2001 | Draft | Request for Information in Narrative Report MS Word Format. | King, Colleen, Healthnow; Eiler, Cheryl, Anthem; Douglass, Barbara, Cigna; Stone, Robin, Palmetto; Douglass, Barbara, Cigna | Government Benefits Administrator | | | | DP Deliberative Process |
| AWP902-04880488 | 6/17/1997 | Memo | CMD Steering Committee Conference Call Minutes (with Notations). Minutes reflect predecisional deliberations of HCFA and Carrier personnel on policy issues. | | | | | | DP Deliberative Process |
| AWP902-04890499 | 10/10/2000 | Report | External Infusion Pumps (Draft of HCPCS Codes) | | | | | | DP Deliberative Process |
| AWP902-05010504 | 7/16/1999 | Policy | Draft Oral Antiemetic Drugs (Replacement for Intervanous Antiemetics) List | | | | | | DP Deliberative Process |
| AWP902-05170522 | 1/31/2000 | Program Memorandum-Carriers | Draft Transmittal Re: New Oral Anti-Cancer Drugs Approved for Use by Medicare | HCFA | | | | | DP Deliberative Process |
| AWP902-05230527 | 7/26/1994 | Composite Draft | Medical Policy re Epoetin | | | | | | DP Deliberative Process |

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| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|-----------------|------------|-------------------------|--|-----------------------------|-----------------|---|--------------------|---|-------------------------|
| AWP902-05300531 | 10/16/1997 | Fax | Region B Suggestions - Medical Policy Change - Erythropoietin - Changes in Coverage and Documentation (Handwritten Notes suggesting changes in draft). | | | | | | DP Deliberative Process |
| AWP902-05320533 | 10/3/1997 | Fax with Attachment | Draft of Region A Medical Policy Change --Erythropoietin. Handwritten notes suggesting changes in draft. | Bach, Debra, DMERC Region A | RN | McNab, Janice, Region B; Mekkelson, Alice, Region B; Wilhelm, Pat, Region C; Rheinecker, Mary, Region D; Majors, Elizabeth, SADMERC | | | DP Deliberative Process |
| AWP902-05340534 | 9/11/1997 | Fax | Draft of Region A Medical Policy Change of 09/10/1997 re Erythropoietin | UHC DMERC A | | Region C | | | DP Deliberative Process |
| AWP902-05350540 | 10/22/1994 | Composite Draft | Draft of Medical Policy Coverage and Payment rules re Epoetin | | | | | | DP Deliberative Process |
| AWP902-05410553 | 7/21/1993 | Email with Attachments | Medicare Contractor Regional Bulletin No. 93 -?, Update on Epoetin (with Handwritten Notes). Contains draft letters and comments/notes. | | | | | JTW, TCF, DMS, GIB, DBV | DP Deliberative Process |
| AWP902-05540558 | 10/2/1996 | Survey with Attachments | Revision to National Policy for EPO (with Handwritten Notations). Contains predecisional recommendations and suggestions for policy change. | HCFA/Medicare/ROG | | | | | DP Deliberative Process |
| AWP902-05590560 | 1/14/2004 | Draft | Epoetin and Darbepoetin - New Codes (with Notations) | | | | | | DP Deliberative Process |
| AWP902-05610565 | 6/27/2001 | Draft | Epoetin HCPCS Codes | | | | | | DP Deliberative Process |
| AWP902-05660567 | 4/9/2002 | Email | E-mail discussing draft LMRP on Epoetin language. | Oleck, Adrian, Anthem | | Warren, J, CMS; Ballantine, L, HCFA; Spalding, J, HCFA | | Collins, Nita; Brazell, Nancy; Valdieso, Grace; Hoover, Robert, Cigna; Hughes, Paul, Tricenturion; Majors, Elizabeth, PGBA; Metzger, Paul, PGBA; Nelson, Kenneth, PGBA; Hutter, Jennifer, PGBA; Bridges, Phyllis, Tricenturion; Rheinecker, Mary, Cigna; Walker, Berta, PGBA; Souza, Sharon, Tricenturion; Craven, Charlene, PGBA | DP Deliberative Process |
| AWP902-05680569 | 4/9/2002 | Email | E-mail discussing draft LMRP on Epoetin language. | Hidit, Renee, CMS | | Oleck, Adrian, Anthem; Spalding, Joann, CMS; Warren, John, CMS; Ballantine, Lorrie, CMS | | | DP Deliberative Process |
| AWP902-05700571 | 4/9/2002 | Email | E-mail discussing draft LMRP on Epoetin language. | Warren, John, CMS | | Oleck, Adrian, Anthem; Spalding, Joann, CMS; Warren, John, CMS; Ballantine, Lorrie, CMS | | | DP Deliberative Process |

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| Document Number | Date | Type | Description | Author | Author Position | Addressee | Addressee Position | Copyee | Privileged Designation |
|-----------------|------------|---------------------------|--|--|--|--|------------------------|---|---|
| AWP902-05720573 | 4/25/2002 | Email | E-mail discussing draft LMRP on Epoetin language. | Oleck, Adrian, Anthem | | Collins, Nita; Brazell, Nancy; Valdivieso, Grace; Hoover, Robert, Cigna; Hughes, Paul, Tricenturion; Majors, Elizabeth, PGBA; Metzger, Paul, PGBA; Nelson, K, PGBA; Hutter, Jennifer, PGBA ; Bridges, Phyllis, Tricenturion, Rheinecker, Mary, Cigna; Walker, Berta, PGBA; Souza, Sharon, Tricenturion; Craven, Charlene, PGBA | | | DP Deliberative Process |
| AWP902-05740577 | 5/24/2002 | Draft Policy | Draft #5 Re: Epoetin HCPCS Codes | | | | | | DP Deliberative Process |
| AWP902-05780582 | 7/26/1994 | Composite Draft | Medical Policy re: Epoetin | | | | | | DP Deliberative Process |
| AWP902-05830588 | 10/22/1994 | Composite Draft | Medical Policy re: Epoetin (with Handwritten Notes) | | | | | | DP Deliberative Process |
| AWP902-05890589 | 10/25/1994 | Draft Bulletin Article | Oral Anticancer Drugs Benefit - New Drug | | | | | | DP Deliberative Process |
| AWP902-05900591 | 1/19/1994 | Memo | Re: Oral Cancer Drugs coverage policy options (Handwritten Notes reflecting opinion on policy options | Oleck, Adrian, AdminaStar Federal | | Arney, Steve, Region V | DMERC Medical Director | | DP Deliberative Process |
| AWP902-05980602 | 1/16/1995 | Memo with Attachments | External Infusion Pumps RMRP Comment & Review Distribution Action Item A-357-2 (with Handwritten Notes commenting upon Composite draft). | Allen, Martina | | Archibald, Ann | | | DP Deliberative Process |
| AWP902-06150617 | 6/12/1995 | Memo | Comments and suggestions concerning Infusion Pump Draft RMRP | Zone, Bob | Medical Doctor | DMERC Medical Directors | | | DP Deliberative Process |
| AWP902-06180625 | 11/18/1994 | Draft | DMERC Proposed Regional Medical Review Policy re External Infusion Pumps (with Handwritten Notes) | | | | | | DP Deliberative Process |
| AWP902-06260637 | 12/18/2003 | Subpoena with Attachments | Inspection and Copying of Documents on Schedule A, Civil Case MDL No.: 1456, Case Number: Civil Action No. 01-CV-12257PBS (D. Mass) | Hobart, Jeffrey, Hobart, Holland & Knight | Issuing Officer | United Healthcare, Medicare Part B | Custodian of Records | | DP Deliberative Process |
| AWP902-06660666 | 1/2/2004 | Memo | Document Describing Carrier Subpoenas Seeking Documents Related to Pharmaceutical Litigation | Walters, Gerald, CMS; Carson, Gregory, CMS | Director, Medicare Contractor Management Group | All Medicare Carriers and Durable Medical Equipment Regional Carriers | | All Ras; All CCMO's; Polise, Lou, CMM/MCMG; Hinson, Jeff, CMM/MCMG; Rinker, Verne, CMM/MCMG; Walters, Gerald, OFM; Bennett, Carol, OGC; Barsky, Troy, OGC; Connelly, William, OGC; Polston, Mark, OGC | AC Attorney-Client, DP Deliberative Process |
| AWP902-06670673 | 2/2/1994 | Draft | EPO Conference Minutes and Draft policy. Minutes reflect deliberations on policies concerning EPO use. | | | | | | DP Deliberative Process |

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|-----------------|----------|-----------------------|--|--|-----------------|---|--------------------|--------|-------------------------|
| AWP902-06740680 | 2/8/1994 | Memo with Attachments | Re: Unlabeled EPO Use - Proposed Drsft Policy and Conference Minutes | Mohs, Frank, General American Life Insurance Company | | TAC Ad Hoc Committee on Unlabeled EPO Use | | | DP Deliberative Process |